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Excelsior Medical Corporation

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IVERA MEDICAL CORPORATION, Plaintiff/Counterclaim Defendant, v. EXCELSIOR MEDICAL CORPORATION, Defendant/Counterclaim Plaintiff.	Case No. 3:11-cv-01115-H-JMA **DEFENDANT'S ANSWER TO FIRST AMENDED COMPLAINT AND FIRST AMENDED COUNTERCLAIMS** **JURY TRIAL DEMANDED**

Defendant Excelsior Medical Corporation ("Excelsior") answers the first amended complaint of plaintiff Ivera Medical Corporation ("Ivera") and asserts certain counterclaims as follows:

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San Diego, California 92130

PARTIES

1. Excelsior lacks information sufficient to form a belief regarding the allegation that Ivera is a California corporation, and therefore denies the same. Upon information and belief, the address given by Ivera as its "principal place of business" is UPS Store #0866. Excelsior denies that this address is Ivera's principal place of business.

2. Excelsior admits the allegations set forth in this paragraph and additionally states that Excelsior is a Delaware corporation.

JURISDICTION

3. Denied.

4. Denied.

BACKGROUND

5. Excelsior lacks information sufficient to form a belief regarding the allegations in this paragraph and therefore denies the same.

6. Excelsior admits that the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 7,780,794 B2 (the "'794 patent"), entitled "Medical Implement Cleaning Device," on August 24, 2010 and that a copy of the '794 patent is attached to the First Amended Complaint as Exhibit A. Except as expressly admitted, Excelsior lacks information sufficient to form a belief regarding the remaining allegations in this paragraph and therefore denies the same.

7. Excelsior lacks information sufficient to form a belief regarding the allegations in this paragraph and therefore denies the same.

8. Excelsior admits that the USPTO issued U.S. Patent No. 7,985,302 B2 (the "'302 patent"), entitled "Medical Implement Cleaning Device," on July 26, 2011 and that a copy of the '302 patent is attached to the First Amended Complaint as Exhibit B. Except as expressly admitted, Excelsior lacks information sufficient to form a belief regarding the remaining allegations in this paragraph and therefore denies the same.

9. Excelsior lacks information sufficient to form a belief regarding the allegations in this paragraph and therefore denies the same.

10. Excelsior admits that it sells a product under the trademark SwabCap within the United States, but denies the remaining allegations of this paragraph.

FIRST CAUSE OF ACTION

COUNT I

(INFRINGEMENT OF THE '794 PATENT)

11. Excelsior incorporates herein by reference each and every response to paragraphs 1 through 10 above, as though set forth here at length.

12. Denied.

13. Denied.

14. Denied.

15. Denied.

SECOND CAUSE OF ACTION

COUNT II

(INFRINGEMENT OF THE '302 PATENT)

16. Excelsior incorporates herein by reference each and every response to paragraphs 1 through 15 above, as though set forth here at length.

17. Denied.

18. Denied.

19. Denied.

20. Denied.

PRAYER FOR RELIEF

Excelsior denies that Ivera entitled to any of the relief requested in its Prayer for Relief and denies any allegations therein.

A. Excelsior denies that Ivera is entitled to the relief requested in this paragraph.

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B. Excelsior denies that Ivera is entitled to the relief requested in this paragraph.

C. Excelsior denies that Ivera is entitled to the relief requested in this paragraph.

D. Excelsior denies that Ivera is entitled to the relief requested in this paragraph.

E. Excelsior denies that Ivera is entitled to the relief requested in this paragraph.

F. Excelsior denies that Ivera is entitled to the relief requested in this paragraph.

G. Excelsior denies that Ivera is entitled to the relief requested in this paragraph.

H. Excelsior denies that Ivera is entitled to the relief requested in this paragraph.

I. Excelsior denies that Ivera is entitled to the relief requested in this paragraph.

AFFIRMATIVE DEFENSES

Excelsior asserts the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE

1. Excelsior has not and is not infringing, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the ’794 and/or ‘302 patents.

SECOND AFFIRMATIVE DEFENSE

2. Any damages are limited by 35 U.S.C. §§ 286 and 287.

THIRD AFFIRMATIVE DEFENSE

3. Ivera’s claims are barred by the equitable doctrines of waiver, estoppel, laches, and unclean hands.

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EXCELSIOR'S PRAYER FOR RELIEF

WHEREFORE, Excelsior respectfully requests that the Court enter judgment against Ivera to include:

A. Entering an order dismissing Ivera's Complaint, with prejudice, and denying Ivera the relief requested in the Complaint and any relief whatsoever.

B. Enter judgment that Excelsior does not infringe, either directly or under the Doctrine of Equivalents, any valid and enforceable claim of the '794 and/or '302 patents.

C. Enter judgment that one or more claims of the '794 and/or '302 patents are invalid.

D. Awarding Excelsior all other such relief as the Court may deem just and proper.

* * *

COUNTERCLAIMS

Counterclaim Plaintiff Excelsior Medical Corp. ("Excelsior") for its First Amended Counterclaims against Counterclaim Defendant Ivera Medical Corp. ("Ivera") hereby alleges as follows:

PARTIES

1. Excelsior is a Delaware corporation with its principal place of business at 1933 Heck Avenue, Neptune, New Jersey 07753.

2. Ivera alleges that it is a California corporation with its principal place of business at 3525 Del Mar Heights Road, Suite 430, San Diego, California, 92130.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because the action involves claims arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

4. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy

within the Court's jurisdiction.

5. This Court has personal jurisdiction over Ivera because, upon information and belief, Ivera is a California corporation that allegedly has a principal place of business within this judicial district.

6. Venue is appropriate in this Court pursuant to 28 U.S.C. § 1391(b)-(c) and 28 U.S.C. § 1400(b) because, upon information and belief, Ivera allegedly resides in this judicial district.

BACKGROUND

7. Excelsior is a leading manufacturer and supplier of products used in the medical field, including a luer access valve disinfection cap sold under the trademark SwabCap.

8. Ivera alleges that it manufactures, markets, and sells Curos® Port Protector, a device that Ivera alleges disinfects and protects the entry port on certain types of valves used with intravenous lines to help reduce bloodstream infections in hospital patients.

9. Upon information and belief, Ivera claims to be the owner of U.S. Patent No. 7,780,794 issued on August 24, 2010 (the "'794 patent"). A true and correct copy of the '794 patent is attached to Ivera's First Amended Complaint as Exhibit A.

10. Upon information and belief, Ivera claims to be the owner of U.S. Patent No. 7,985,302 issued on July 26, 2011 (the "'302 patent"). A true and correct copy of the '302 patent is attached to Ivera's First Amended Complaint as Exhibit B.

THE CONTROVERSY

11. On or about May 6, 2011, Ivera filed a complaint for patent infringement against Excelsior in the United States District Court for the Eastern District of Texas. In its complaint, Ivera alleges that Excelsior's SwabCap products infringe the '794 patent. The case was captioned *Ivera Medical Corp. v. Excelsior*

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Medical Corp., Civil Action No. 6:11-cv-0220-LED (the "Texas Action").

12. Ivera served its complaint in the Texas Action on Excelsior on or about May 10, 2011.

13. However, on May 23, 2011, before Excelsior's answer came due, Ivera filed a Notice of Dismissal under Fed. R. Civ. P. 41(a)(1)(A)(1) dismissing its complaint against Excelsior without prejudice.

14. On or about May 20, 2011, prior to dismissing the Texas Action, Ivera filed the immediate action for patent infringement against Excelsior in this District (the "Immediate Action").

15. In its initial complaint in the Immediate Action, Ivera again alleges that Excelsior's SwabCap products infringe the '794 patent.

16. Ivera amended its complaint in the Immediate Action on September 14, 2011 to allege that Excelsior's SwabCap products also infringe the '302 patent.

17. The '794 and '302 patents are referred to collectively in this First Amended Counterclaims as the "Asserted Patents."

18. Accordingly, there is an actual, substantial and continuing justiciable case and controversy between Excelsior and Ivera regarding the Asserted Patents, over which this Court can and should exercise jurisdiction, and declare the rights of the parties. Excelsior is therefore entitled to bring and maintain these counterclaims for declaratory judgment. 28 U.S.C. §§ 2201.

COUNT I

(Declaratory Judgment of Non-Infringement of the '794 Patent)

19. Excelsior incorporates the allegations of paragraphs 1-18 as if set forth herein in full.

20. Excelsior has not and is not infringing, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '794 patent.

21. Excelsior is therefore entitled to a declaratory judgment that it has not and is not infringing any valid and enforceable claim of the '794 patent.

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COUNT II

(Declaratory Judgment Of Invalidity of the '794 Patent)

22. Excelsior incorporates the allegations of paragraphs 1-21 as if set forth herein in full.

23. One or more of the claims of the '794 patent are invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

24. Excelsior is therefore entitled to a declaratory judgment that one or more of the claims of the '794 patent are invalid.

COUNT III

(Declaratory Judgment of Non-Infringement of the '302 Patent)

25. Excelsior incorporates the allegations of paragraphs 1-24 as if set forth herein in full.

26. Excelsior has not and is not infringing, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '302 patent.

27. Excelsior is therefore entitled to a declaratory judgment that it has not and is not infringing any valid and enforceable claim of the '302 patent.

COUNT IV

(Declaratory Judgment Of Invalidity of the '302 Patent)

28. Excelsior incorporates the allegations of paragraphs 1-27 as if set forth herein in full.

29. One or more of the claims of the '302 patent are invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

30. Excelsior is therefore entitled to a declaratory judgment that one or more of the claims of the '302 patent are invalid.

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COUNT V

(Declaratory Judgment of Patent Unenforceability)

31. Excelsior incorporates the allegations of paragraphs 1-30 as if set forth herein in full.

32. The Asserted Patents are unenforceable due to inequitable conduct by Bobby E. Rogers and Paul Diperna, the named inventors of the Asserted Patents ("Inventors"), and/or others involved in the prosecution of the corresponding applications of the Asserted Patents before the USPTO.

33. The Inventors and/or others involved in the prosecution of the Asserted Patents failed to disclose material, non-cumulative prior art with specific intent to deceive.

34. The Inventors are also the named inventors of another application, U.S. patent application Serial No. 12/791,809 (the "'809 application") filed on June 1, 2010 and entitled "Medical Implement Cleaning Device with Friction-Based Fitting."

35. According to the assignment database maintained by the USPTO, the Inventors assigned the '809 application to Ivera.

36. Like each of the Asserted Patents, the '809 application is also directed to a cleaning device which includes a cap.

37. In fact, the '809 application purports to incorporate by reference the application that matured into the '794 patent in its disclosure: "[a] cleaning device 210 in the form of a cap, is sized and adapted to clean the female connection 204, as exemplified in U.S. patent application Ser. No. 11/705,805, filed Feb. 12, 2007, the contents of which are incorporated herein by reference for all purposes." U.S. patent application Ser. No. 11/705,805 is the corresponding application to the '794 patent.

38. Accordingly, the Inventors were well aware of the '809 application and its relation to the Asserted Patents.

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39. During prosecution of the '809 application, the Inventors filed an Information Disclosure Statement (IDS) on August 12, 2010. A copy of this IDS is attached hereto as **Exhibit A**.

40. In the IDS filed in the '809 application prosecution, the Inventors disclosed, *inter alia*, the following references that they discovered in an International Search Report performed in conjunction with prosecution of the international counterpart to the '809 application:

a. U.S. Publication No. 2008/0132880, published June 5, 2008, to Buchman (attached hereto as **Exhibit B**); and

b. U.S. Patent No. 4,440,207, issued April 3, 1984 to Genatempo et al. (attached hereto as **Exhibit C**).

41. Both Buchman and Genatempo et al. disclosed in this IDS are material to the Asserted Patents.

42. As to the '794 patent, all of the independent claims include a venting feature or a variation thereof. For example,

(a) Claim 1 recites "A cleaning device for a medical implement, the cleaning device comprising [*inter alia*] . . . an additional opening in the cleaning device formed between an outside edge of the threaded ring and an inside edge of the inner cavity to allow evaporation of the cleaning agent from the inner cavity and to inhibit a vacuum in the cap when the first opening receives the site of the medical implement."

(b) Claim 5 recites "A cleaning system for a threaded medical implement, the cleaning system comprising [*inter alia*] . . . one or more vent holes between the threaded ring and the inner cavity at the opening to the cap, the one or more vent holes to permit drying the cleaning agent and to inhibit a vacuum in the inner cavity to support mechanical tension by the threads on the threaded medical implement."

(c) Claim 12 recites "A method of cleaning a site of a medical

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implement, the method comprising [*inter alia*]…evaporating the cleaning agent through the at least one other aperture to the inner cavity as the cap is attached over the top of the site."

(d) Claim 13 recites "A cleaning device for a medical implement, the cleaning device comprising [*inter alia*] . . . a second opening in the cap to allow evaporation of the cleaning agent from the inner cavity and to inhibit a buildup of pressure in the cap…"

(e) Claim 19 recites "A cleaning system for a medical environment, the cleaning system comprising [*inter alia*] . . . at least one evaporation vent in a wall of the cap between the threaded ring and the inner cavity at the opening to allow evaporation of the cleaning agent upon receipt of the site of the medical implement…"

(f) Claim 20 recites "A cleaning device for a medical implement, the cleaning device comprising [*inter alia*] . . . at least one second opening proximate the opening to the inner cavity to allow evaporation of the cleaning agent from the inner cavity and to inhibit a vacuum in the cap when the opening receives the site of the medical implement…"

(g) Claim 23 recites "A cleaning device for a medical implement, the cleaning device comprising [*inter alia*]. . . means for venting the cleaning agent from the compressible cleaning material and the inner cavity, the means for venting being created between the cap and the site of the medical implement when the site of the medical implement is received in the opening of the cap..."

43. Buchman teaches or suggests a cap design that contains a body and a connector/top, which includes, *inter alia*, a venting feature that is provided across the threads through the sponges, the pores thereof, the channels in which the sponges sit, and the spaces formed by the sponges between the threads.

44. Buchman therefore is material to at least the following limitations of the independent claims of the '794 patent because Buchman discloses a venting

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feature: (a) the "to allow evaporation of the cleaning agent" limitation recited in Claim 1; (b) the "to permit drying the cleaning agent" limitation recited in Claim 5; (c) the "evaporating the cleaning agent through the at least one other aperture" limitation recited in Claim 12; (d) the "to allow evaporation of the cleaning agent" limitation recited in Claim 13; (e) the "to allow evaporation of the cleaning agent" limitation recited in Claim 19; (f) the "to allow evaporation of the cleaning agent" limitation recited in Claim 20; and (g) the "means for venting" limitation recited in Claim 23.

45. Buchman is not cumulative of any other references considered by the USPTO during prosecution of the '794 patent because Buchman teaches or suggests the venting feature of Claims 1, 5, 12, 13, 19, 20, and 23 of the '794 patent, *e.g.*, Buchman teaches or suggests venting through the sponges, the pores thereof, the channels in which the sponges sit, and the spaces formed by the sponges between the threads, whereas said teachings were not of record in the '794 patent.

46. Genatempo et al. discloses an antibacterial protective cap for catheter connectors, which also teaches or suggests that a partial seal alone is sufficient. More specifically, Genatempo et al. states the following:

> Skirt 18 may be proportioned to form a tight, annular seal area 46 with flange 36. Annular step or shoulder 48 ***may also*** be provided in skirt 18 and positioned to engage flange 36 for ***added sealing***, and also to prevent over advancement of connector 32 into cap 10, which could damage the respective threads 42, 38.

Genatempo et al., C. 3, L. 46 through C. 3, L. 51 (emphasis added). Genatempo et al. contemplates the provision of a seal. However, the teachings of Genatempo et al., in using the language "added sealing," acknowledges that ***sealing is a question of degree.*** As such, Genatempo et al. teaches at least two different "versions" of an antibacterial cap: a first version with less sealing structure that allows for greater

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leakage/venting; and a second version with more structure that allows for lesser leakage/venting.

47. Genatempo et al. therefore is material to at least the following limitations of the independent claims of the '794 patent because Genatempo et al. teaches that added sealing is optional and therefore suggests that less than absolute sealing is optional: (a) the "to allow evaporation of the cleaning agent" limitation recited in Claim 1; (b) the "to permit drying the cleaning agent" limitation recited in Claim 5; (c) the "evaporating the cleaning agent through the at least one other aperture" limitation recited in Claim 12; (d) the "to allow evaporation of the cleaning agent" limitation recited in Claim 13; (e) the "to allow evaporation of the cleaning agent" limitation recited in Claim 19; (f) the "to allow evaporation of the cleaning agent" limitation recited in Claim 20; and (g) the "means for venting" limitation recited in Claim 23.

48. Genatempo et al. is not cumulative of any other references considered by the USPTO during prosecution of the '794 patent because Genatempo et al. teaches or suggests the venting feature of Claims 1, 5, 12, 13, 19, 20, and 23 of the '794 patent, *e.g.*, Genetempo et al. includes an express teaching that less than absolute sealing is optional, whereas said express teaching was not of record in the '794 patent.

49. As to the '302 patent, all of the independent claims include a venting feature or a variation thereof. For example,

(a) Claim 1 recites: "A cleaning device for a medical implement, the cleaning device comprising [*inter alia*] . . . at least one aperture to the inner cavity to allow venting from the inner cavity when the opening receives the site of the medical implement…"

(b) Claim 7 recites: "A cleaning device for a medical implement, the cleaning device comprising [*inter alia*] . . . at least one aperture to the inner cavity to allow venting from the inner cavity when the inner cavity receives the site of the

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medical implement…"

(c) Claim 13 recites "A cleaning device for a medical implement, the cleaning device comprising [*inter alia*] . . . at least one aperture to the inner cavity to allow venting from the inner cavity when the cap covers the site of the medical implement…"

50. Based on the same disclosure recited *supra*, Buchman therefore is material to at least the "at least one aperture to the inner cavity to allow venting" limitations recited in Claims 1, 7, and 13 of the '302 patent because Buchman discloses a venting feature.

51. Buchman is not cumulative of any other references considered by the USPTO during prosecution of the '302 patent because Buchman teaches or suggests the venting feature of Claims 1, 7, and 13 of the '302 patent, *e.g.*, Buchman teaches or suggests venting through the sponges, the pores thereof, the channels in which the sponges sit, and the spaces formed by the sponges between the threads, whereas said teachings were not of record in the '302 patent.

52. Based on the same disclosure recited *supra*, Genatempo et al. therefore also is material to the "at least one aperture to the inner cavity to allow venting" limitations recited in Claims 1, 7, and 13 of the '302 patent because Genatempo et al. notes that added sealing is optional and therefore suggests that less than absolute sealing is optional.

53. Genatempo et al. is not cumulative of any other references considered by the USPTO during prosecution of the '302 patent because Genatempo et al. teaches or suggests the venting feature of Claims 1, 7, and 13 of the '302 patent, *e.g.*, Genetempo et al. includes an express teaching that less than absolute sealing is optional, whereas said express teaching was not of record in the '302 patent.

54. Accordingly, the Buchman and Genatempo et al. references disclosed in the IDS filed during prosecution of the '809 application were material, non-cumulative prior art to the Asserted Patents.

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55. Buchman and Genatempo et al., however, despite being disclosed during prosecution of the '809 application and before the Asserted Patents had issued, were never disclosed to the USPTO during prosecution of the Asserted Patents.

56. As the inventors of the '809 application (Rogers and Diperna) are the same inventors of the Asserted Patents, the Inventors were clearly aware of Buchman and Genatempo et al.

57. The Inventors and others involved in prosecution of the Asserted Patents were clearly aware of the materiality of these references to the Asserted Patents because the Inventors saw fit to disclose Buchman and Genatempo et al. in an IDS during prosecution of the '809 application, an application directed to the same subject matter as the Asserted Patents and one that incorporated the corresponding application of the '794 patent by reference.

58. The inference is compelling that the Inventors' failure to disclose Buchman and Genatempo et al. during prosecution of the Asserted Patents was the result of a specific intent to deceive the USPTO because the Inventors and others involved in the prosecution of the Asserted Patents were clearly aware of the materiality and non-cumulative nature of Buchman and Genatempo et al., and disclosed them during prosecution of another application directed to a similar invention.

59. Given the materiality and non-cumulative nature of these references discussed *supra*, the Asserted Patents would not have issued but for the Inventors' failure to disclose Buchman or Genatempo et al., either alone or in combination with other references.

60. Had the USPTO been provided a copy of Buchman and/or Genatempo et al., the Asserted Patents would not have issued.

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PRAYER FOR RELIEF

WHEREFORE, Excelsior respectfully requests that the Court enter judgment against Ivera to include:

A. Declaring that Excelsior has not infringed, either directly or under the Doctrine of Equivalents, any valid and enforceable claim of the Asserted Patents;

B. Declaring that one or more of the claims of the Asserted Patents are invalid;

C. Declaring that the Asserted Patents are unenforceable due to inequitable conduct;

D. Awarding Excelsior all other such relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Defendant Excelsior hereby demands a jury trial as to all issues that are so triable.

Respectfully submitted.

Date: September 26, 2011

SHEPPARD MULLIN RICHTER & HAMPTON LLP
Robert S. Gerber

By: /s/

Attorneys for Defendant/Counterclaim Plaintiff Excelsior Medical Corporation

INDEX OF EXHIBITS

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San Diego, California 92130

EXHIBIT A

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).
Dated: 8/12/2010 Signature: _____ (Jonathan V. Ong)

Docket No.: 35839-503001US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Bobby E. Rogers et al.

Application No.: 12/791,809 | Confirmation No.: 3403

Filed: June 1, 2010 | Art Unit: 3767

For: Medical Implement Cleaning Device with Friction-Based Fitting | Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications.

Applicant(s) have become aware of the following documents, cited in an International Search Report issued July 29, 2010, during the prosecution of International Application No. PCT/US2010/036958, which corresponds to the above referenced application, and in accordance with 37 CFR 1.97(c) and (e)(1) or (b)(3), hereby submit(s) these documents for the Examiner's consideration.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

I hereby certify, pursuant to 37 CFR 1.97(e)(1), that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. Furthermore, in accordance with 37 CFR 1.704(d), Applicant(s) note(s) that to our knowledge this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of this statement.

This statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any document herein be construed *per se* as a representation that such document is prior art. Moreover, Applicant(s) understand(s) the Examiner will make an independent evaluation of the cited documents.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0311, under Order No. 35839-503001US.

Dated: 6/12/2010

Respectfully submitted,

By _____

James P. Cleary, Esq.
Registration No.: 45,843
MINTZ LEVIN COHN FERRIS GLOVSKY AND POPEO, P.C.
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Used in Lieu of PTO/SB/08A/B
(Based on PTO 11-07 version)

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	12/791,809
Filing Date	June 1, 2010
First Named Inventor	Bobby E. Rogers
Art Unit	3767
Examiner Name	Not Yet Assigned
Attorney Docket Number	35839-503001US

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A*	US-20080019889	01-24-2008	Rogers et al.	
	B*	US-20080177250	07-24-2008	Howlett et al.	
	C*	US-20080132880	06-05-2008	Buchman	
	D*	US-4,440,207	04-03-1984	Genatempo et al.	
	E*	US-20090137969	05-28-2009	Colantonio et al.	
	F*	US-5,169,033	12-08-1992	Shay	
	G*	US-20090028750	01-29-2009	Ryan	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

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Application No. (if known): 12/791,809 Attorney Docket No.: 35839-503001US

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IDS (Citation) by Applicant (7 References) (1 page)

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(12) **Patent Application Publication**

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(54) **CATHETER CLEANING DEVICES**

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(21) Appl. No.: **11/706,517**

(22) Filed: **Feb. 14, 2007**

Related U.S. Application Data

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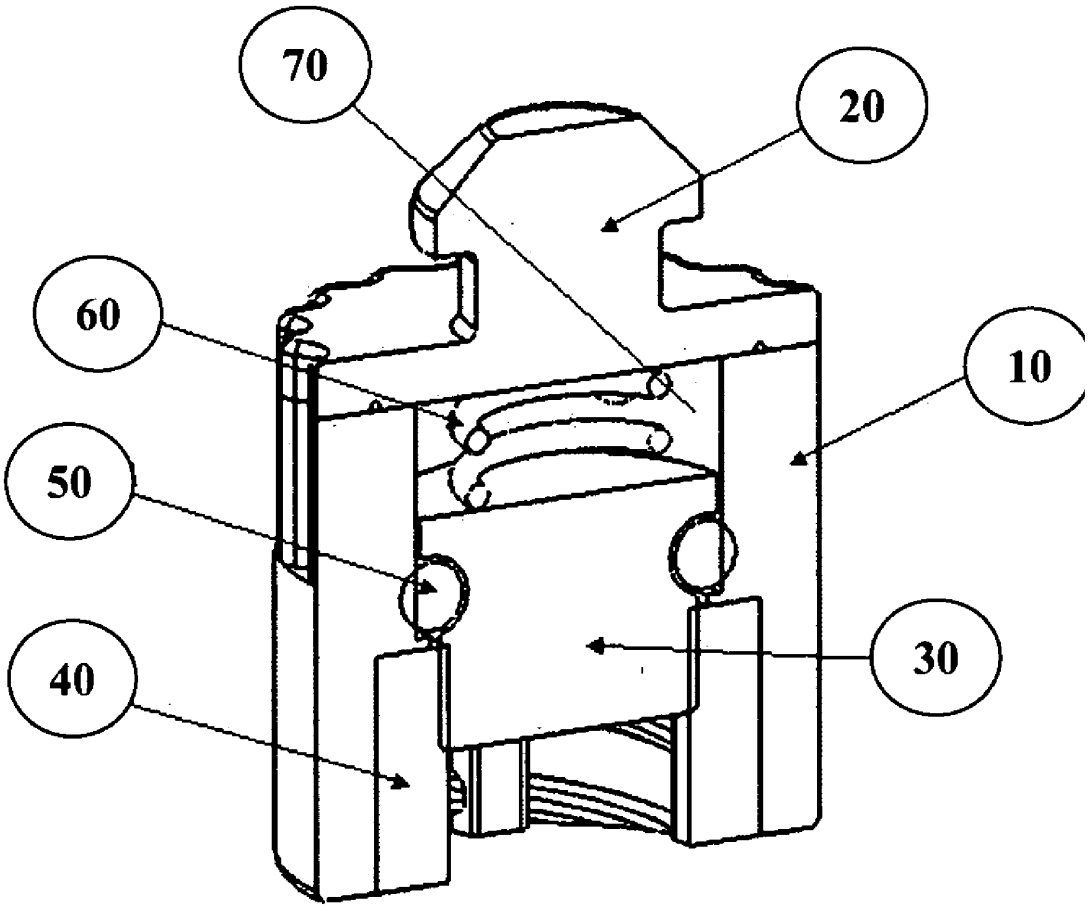
Publication Classification

(51) **Int. Cl.**
A61M 39/02 (2006.01)

(52) **U.S. Cl.** **604/533**; 15/105

(57) **ABSTRACT**

The present invention provides catheter cleaning devices that are effective at reducing microbial contamination of a catheter port entry. For example, the invention provides a catheter, a catheter cleaning device and a catheter cleaning injection port cap, each of which reduces potential microbial contamination at a catheter port entry.



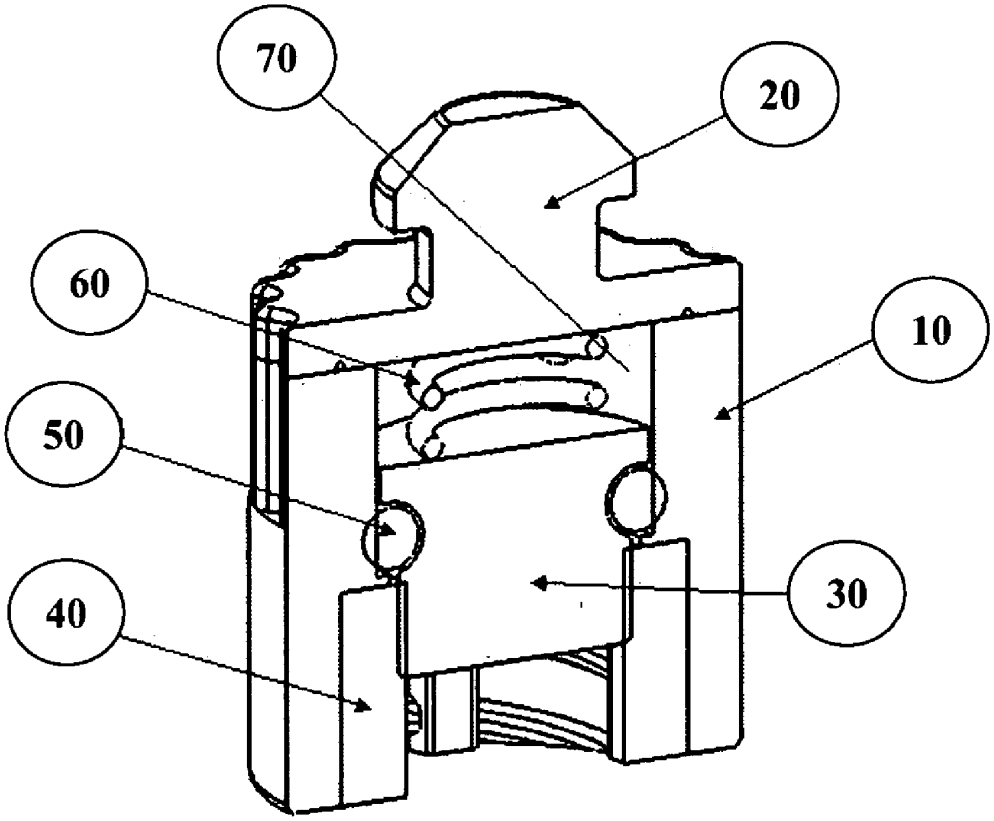


FIGURE 1

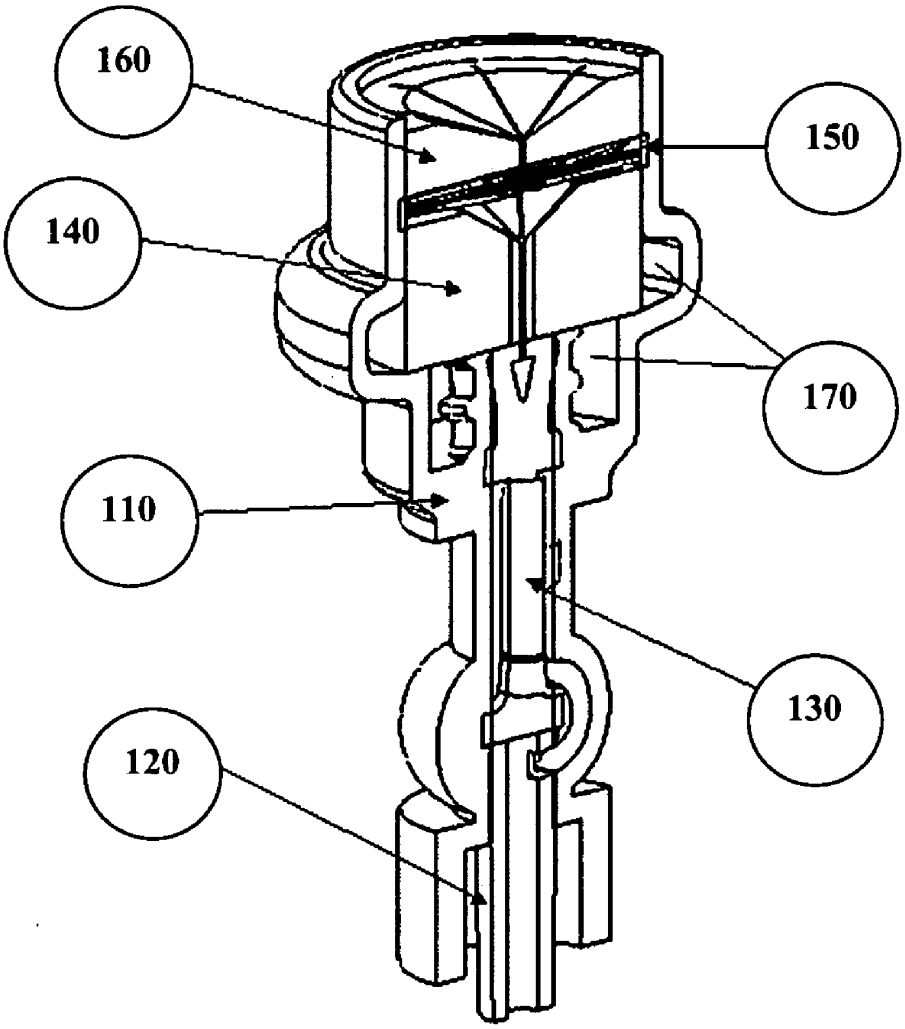


FIGURE 2

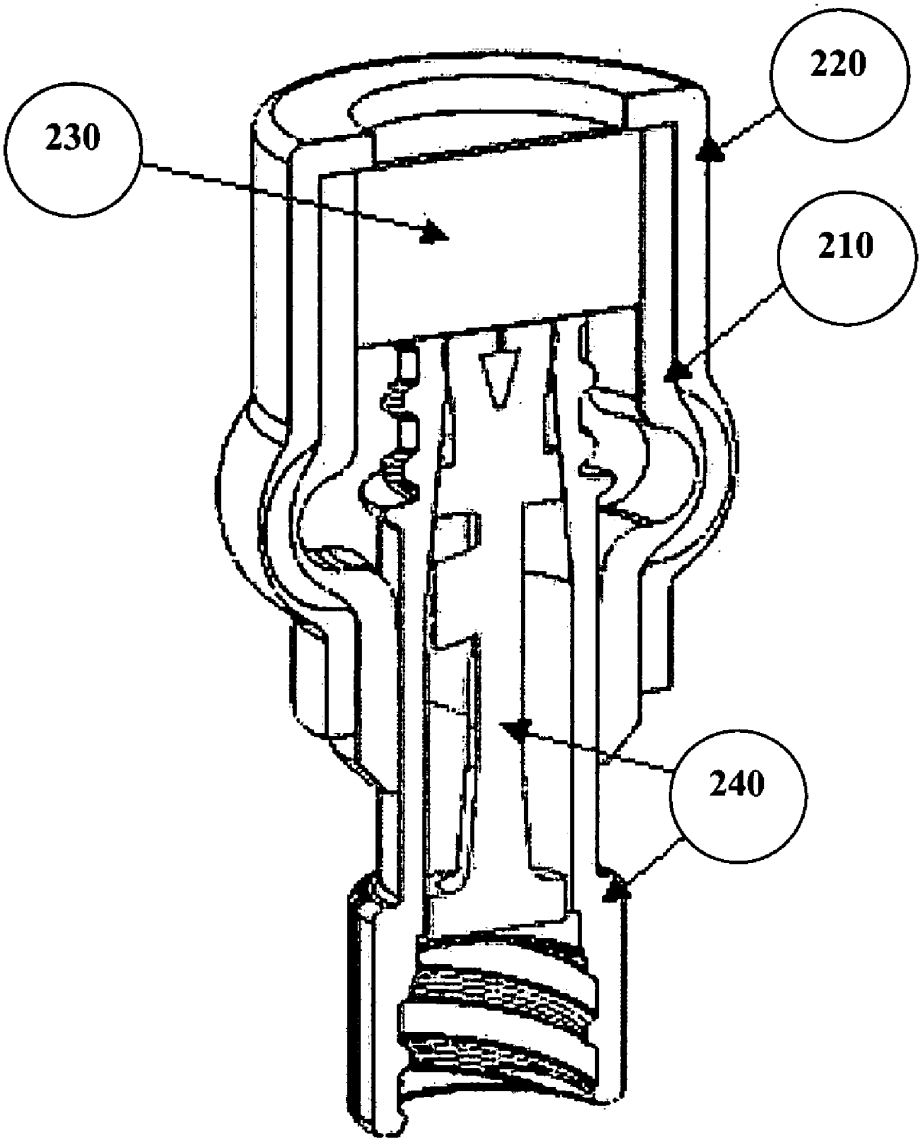


FIGURE 3

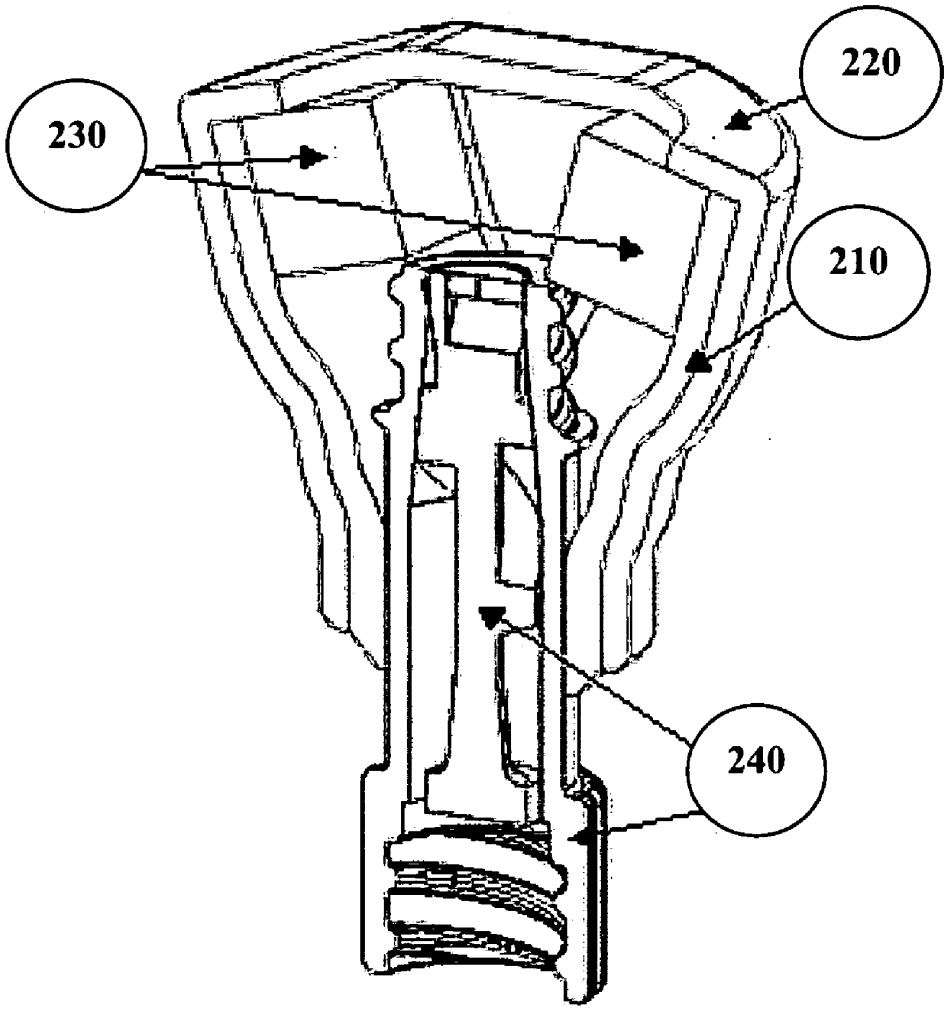


FIGURE 4

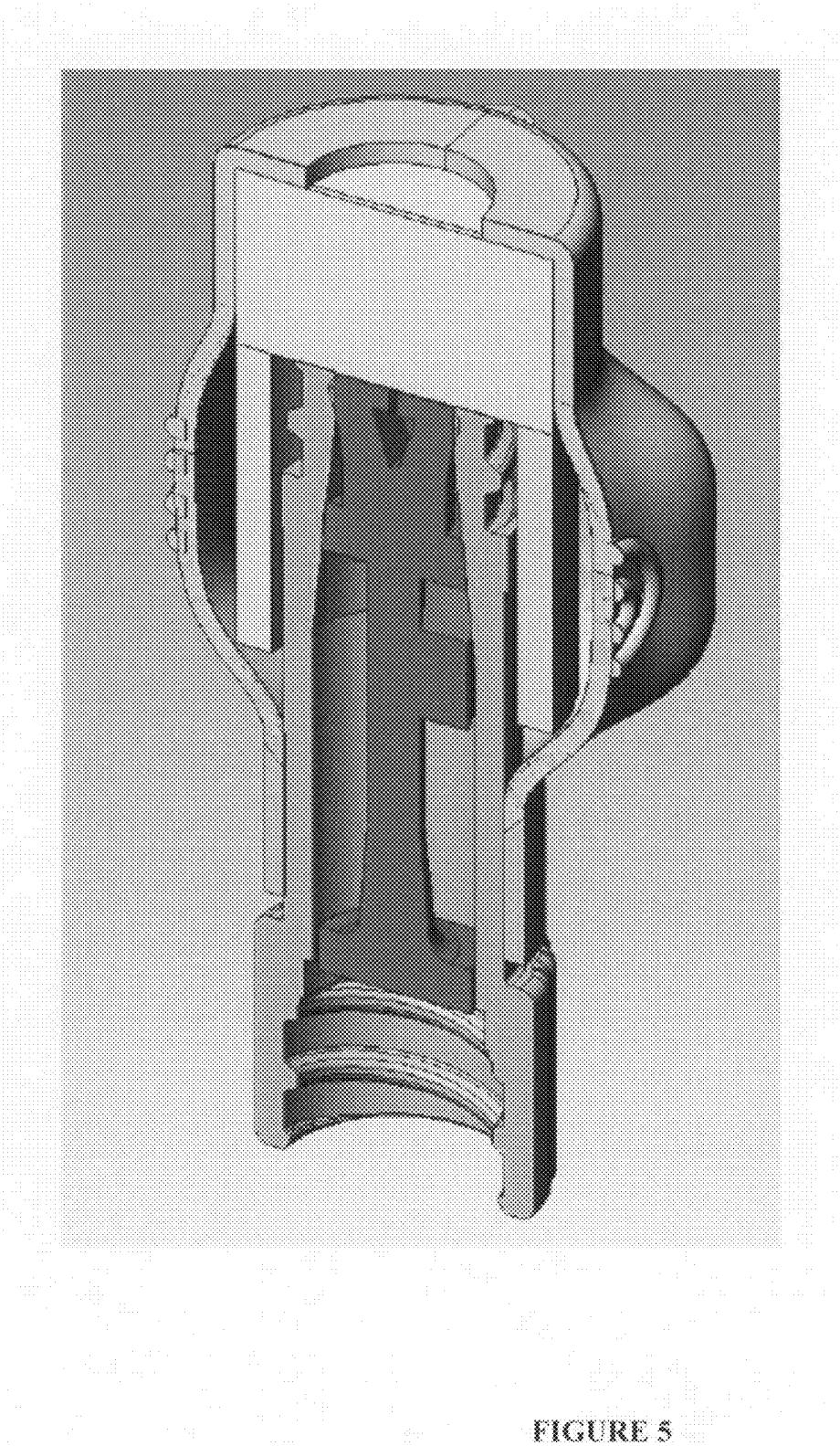


FIGURE 5

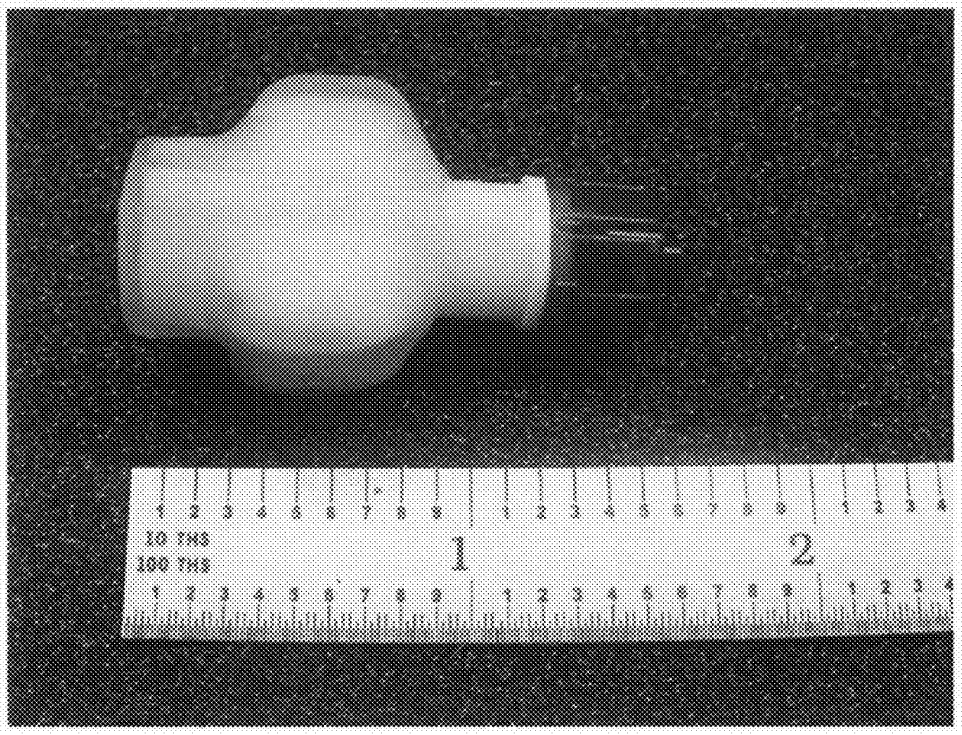


FIGURE 6

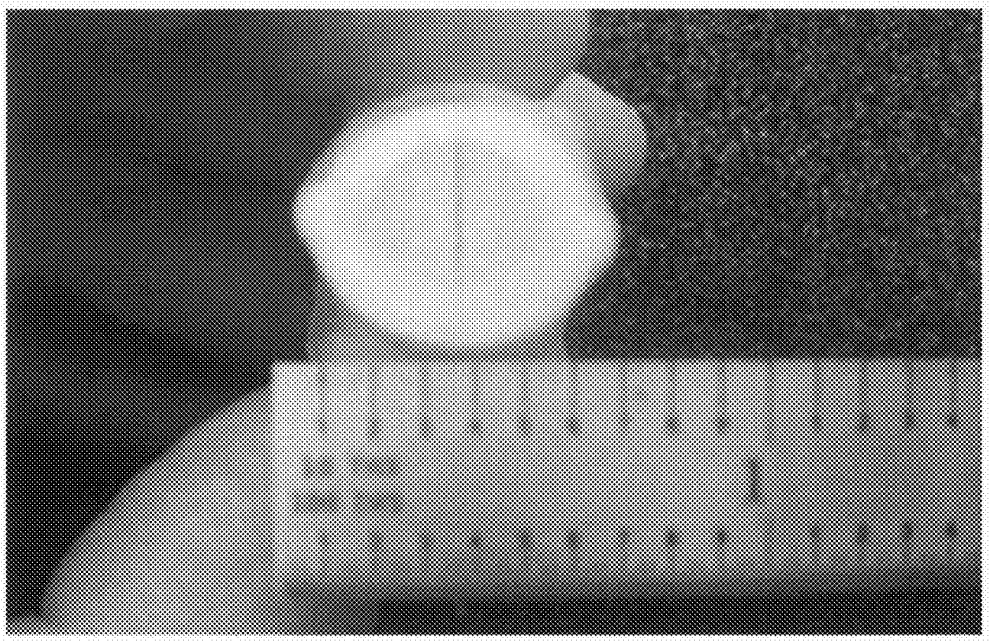


FIGURE 7

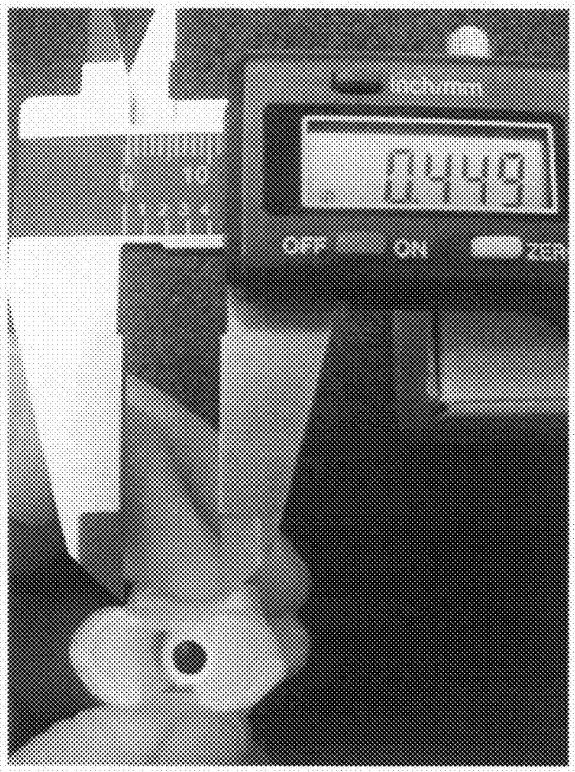


FIGURE 8

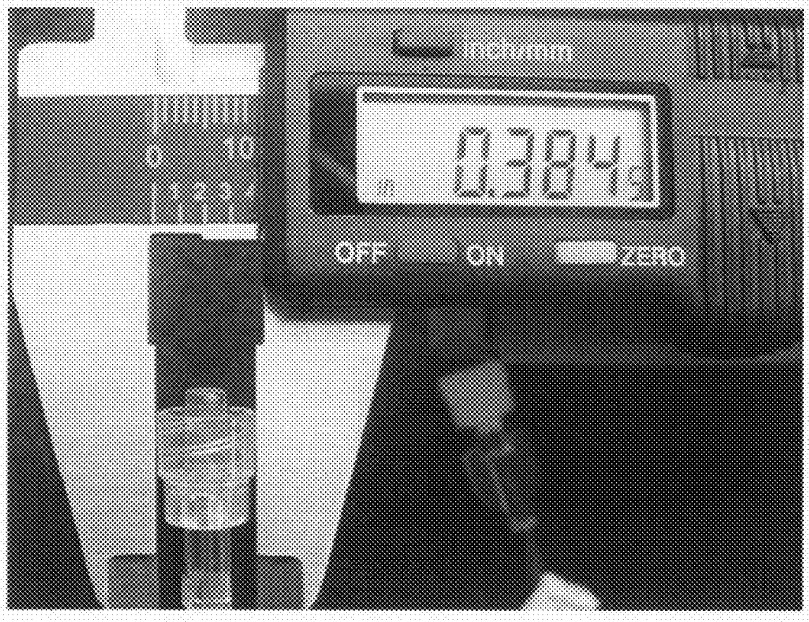


FIGURE 9

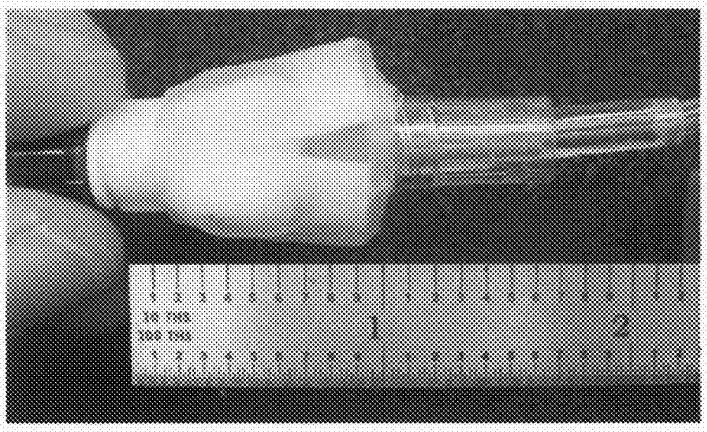


FIGURE 10

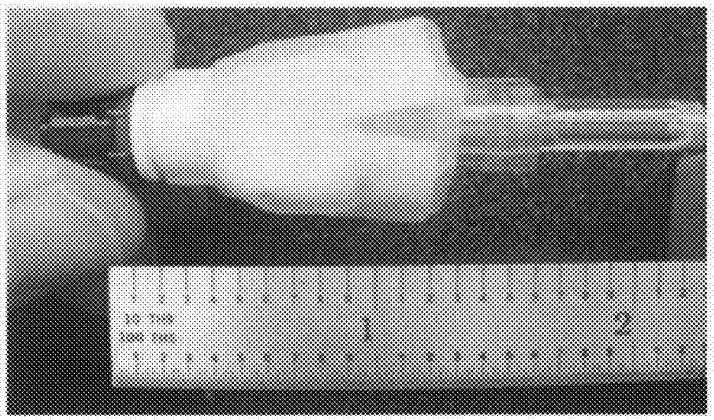


FIGURE 11

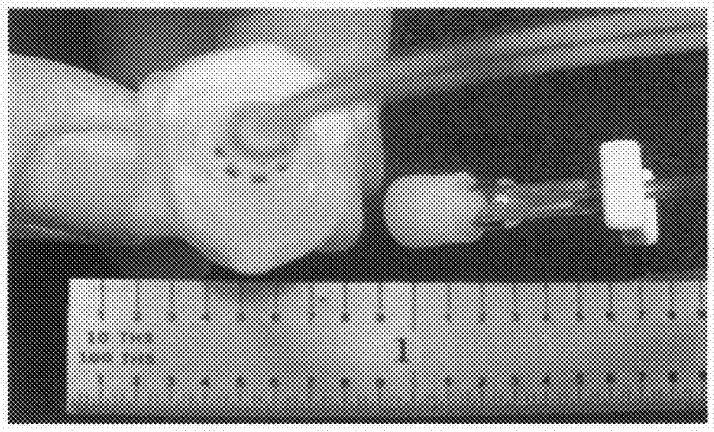


FIGURE 12

CATHETER CLEANING DEVICES

[0001] This application claims the benefit of priority of application Ser. No. 60/774,708, filed Feb. 17, 2006, the entire contents of which is incorporated herein by reference.

[0002] This application relates generally to the field of medicine and more specifically to catheter devices.

BACKGROUND OF THE INVENTION

[0003] Central venous catheters (CVCs) are indispensible devices for medical practice, particularly among critically ill patients, cancer patients, and those that receive intravenous feeding. These devices allow for the rapid infusion of concentrated medications, fluids, or blood products that can otherwise not be administered via a standard intravenous catheter inserted into a peripheral extremity vein. Although such catheters supply necessary vascular access, they also put the patient at risk for significant infection, which can be life-threatening.

[0004] There are an estimated 3 million CVCs inserted each year in the USA and 200,000 in Great Britain (Little and Palmer, *Nursing Standard* 12:42-44, 1998). In the USA, such catheters remain in place for an estimated 15 million catheter days (1 catheter in 1 patient for 1 day=1 catheter day) in ICUs alone (Mermel, *Ann. Intern. Med.* 132:391-402 (2000). Catheter-related bloodstream infection is the most frequent cause of hospital-acquired bacteremia (Valles et al. *Clin. Infect. Dis.* 24:387-395 (1997). 80,000-400,000 central venous catheter (CVC)-related bloodstream infections (CRBI) occur in the USA annually, hospital stay is prolonged by an average of a week, and 2,400-60,000 patients die (Mermel, *Ann. Intern. Med.* 132:391-402 (2000); Raad and Darouiche, *Curr. Opin. Crit. Care* 2:361-3651996; Arnow et al., *Clin. Infect. Dis.* 16:778-784 (1993); CDC, National Nosocomial Infections Surveillance System (NNIS) report, data summary from October 1986-April 1998, issued June, 1998. *Am. Infect. Control* 26:522-533, (1998); Digiovine et al., *Am. J. Respir. Crit. Care Med.* 160:976-981 (1999); Rello et al., *Am. J. Respir. Crit. Care Med.* 162:1027-1030 (2000); Soufir et al., *Infect. Control Hosp. Epidemiol.* 20:396-401 (1999); Kluger and Maki, Abstracts of the 39th Interscience Conference on Antimicrobial Agents and Chemotherapy. San Francisco, Calif.: American Society for Microbiology, 514 (1999)). Estimates of the annual cost of caring for the CVC-related infections in these patients ranged from $296 million to $2.3 billion in 2000 (Mermel, *Ann. Intern. Med.* 133:395 (2000)). The use of needleless catheter devices has been associated with an increased risk for bloodstream infection (Kellerman et al., *J. Pediatr.* 129:711-717 (1996); Do et al., *J. Infect. Dis.* 179:442-448, (1999)).

[0005] Most catheter-related bloodstream infections (CRBI) associated with the use of long-term catheters (>10 days) stem from endoluminal contamination and subsequent colonization of the catheter hub. The hub may become contaminated when microorgansims are present on the external hub surface from contact with the patient's skin, tracheostomy secretions, wounds, ostomy and feces, and the like, or from transfer to the hub surface from the physician or nurse manipulating the catheter (Cicco et al., *Lancet* 2:1258-1260 (1989)). Most episodes of CRBI are caused by coagulase negative staphylococci, *Staphylococcus aureus,* enterococci species, *Klebsiella pneumonia, Escherichia coli,* and *Candida* species (CDC. Guidelines for the prevention of intravascular catheter-related infections. *MMWR* 51:1-29, (2002)).

[0006] The catheter hub (junction of the catheter and intravenous tubing) has been identified as the primary source of CRBI in patients that have an indwelling catheter for >10 days (Sitges-Serra and Linares, *Lancet* 1:668 (1983); Sitges-Serra et al., *Surgery* 97:355-257 (1985); Sitges-Serra et al., *JPEN* 8:668-672 (1984); Linares et al., *J. Clin. Microbiol.* 21:357-360 (1985); Forse et al., *Surgery* 86:507-514 (1979); Moro et al., *Infect. Control Hops. Epidemiol.* 15:253-264 (1994); Llop et al., *Clin. Nutr.* 20:527-534 (2001); Bouza et al., *J. Hosp. Infect.* 54:279-287, (2003); Salzman and Rubin, *Nutrition* 13:15S-17S (1997); Tan et al., *J. Infect. Dis.* 169: 1393-1397 (1994)). The hub is often contaminated during manipulation necessary to draw blood samples, administer medication, fluid, or parenteral nutrition. Microorganisms present on or nearby (ostomy, wound, fistula, skin, tracheostomy, blanket/clothing) the external hub surface are transferred to the hub lumen by the patient's, nurse's, or physician's fingers when the catheter hub is handled (De Cicco et al., *Lancet* 2:1258-1260 (1989)). Even 10-20% of piggyback side-ports punctured six times daily become colonized with pathogenic microorganisms (Brismar et al., *Clin. Nutr.* 6:31-36 (1982).

[0007] Current hub designs were designed primarily to ensure a tight connection with intravenous tubing, but were not designed specifically to prevent hub and endoluminal catheter microbial colonization. Prevention of hub colonization, and therefore of hub-mediated infections is dependent on the avoidance of contamination during connection/disconnection of tubing, during direct injections, and during blood drawing as well as protection against contamination of the hub while connected to tubing. Experimental evidence has shown that intentional hub surface bacterial contamination leads to 100% internal fluid pathway contamination in an inappropriately disinfected hub and that disinfection of the hub cap will prevent up to 99% of potential contamination of the internal fluid pathway (Ardulno et al., *Am. J. Infect. Control* 26:377-380 (1997)). Needleless systems now in current use may also result in increased infection risk when compared to previous needled systems (Danzig et al., *JAMA* 273:1862-1864 (1995); Kellerman et al., *J. Pediatr.* 129:711-717 (1996)). These systems differ from older needle-containing systems by nature of their hub design.

[0008] Therefore, prevention of hub colonization will reduce or prevent the introduction of microorganisms into the catheter lumen. Such prevention may be evoked through careful cleaning and preparation of the catheter prior to use. Often however, such care is less than optimal and, in an emergency situation especially, catheter hubs are not often cleaned appropriately (Stotter et al., *JPEN* 11: 159-162 (1987); Sitges-Serra, *Support Care Cancer* 7:391-395 (1999)). Neither the currently used Luer-lock connector or the rubber membrane "piggyback" system have antimicrobial properties and therefore require strict aseptic manipulation. In addition, proper hub care requires additional training and increases the time required for already constrained health care professionals.

[0009] Thus, there exists a need for techniques and devices that can be effective at reducing microbial contamination of a

catheter connection. The present invention satisfies this need and provides related advantages as well.

SUMMARY OF INVENTION

[0010] The invention provides an injection port cap, comprising a body having a cavity extending from a distal end to a proximate end of the body; a movable frit located within the cavity so as to form a reservoir between the frit and the proximate end of the body; a biasing element arranged to urge the movable frit towards the distal end of the body; and an absorbent element located within the cavity adjacent the distal end of the body.

[0011] The invention also provides a catheter cleaning device comprising a body comprising a passageway extending from a proximate opening adjacent a proximate end to a distal end; a penetrable sealing element located adjacent the proximate end within the passageway; an absorbent element located within the passageway between the distal end and the penetrable sealing element; at least one brush located between the penetrable sealing element and the absorbent element; a luer connector located within the passageway between the distal end and the brushes; and a reservoir formed within the passageway between the luer connector and the penetrable sealing element.

[0012] The invention additionally provides a catheter cleaning injection port cap, comprising a body comprising a passageway extending from a proximate end to a distal end; the proximate end operable in a closed position and an open position; the body further comprising an actuating member configured to change the proximate end from the closed position to the open position; a plurality of separable absorbent elements located within the passageway adjacent the proximal end; and a fluid impermeable sheath covering at least a portion of an exterior of the body.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawings will be provided by the Office upon request and payment of the necessary fee.

[0014] FIG. **1** shows an exemplary catheter cleaning device as a cap design. The cap is made up of two parts, the body **10** and the connector/top **20** as shown in FIG. **1**. The other parts include mobile frit **30**, open cell wiping foam or sponges **40**, O-ring **50**, and spring **60**. Frit **30** forms a reservoir **70** in the cavity of body **10**.

[0015] FIG. **2** shows an exemplary catheter cleaning device as a penetration design. The parts that make up the port of the penetration design include device body **110** with luer threads included for attachment to the central venous catheter (CVC) and the feeding tube or male luer. The other parts include the bottom plug **120** that is in the male luer to the CVC, piston **130**, scrubbing memory open cell foam **140**, scrubbing brushes **150** and sealing foam **160**.

[0016] FIG. **3** shows an exemplary catheter cleaning device as a pop open design. The pop open cap design is made up of three parts, the device body **210**, the fluid sheath **220**, and scrubbing/bathing foam **230**. Also shown is a separate luer activated needleless valve/port/connector **240**. The position depicted is the "closed" position.

[0017] FIG. **4** shows the catheter cleaning device shown in FIG. **3** depicted in the "open" position.

[0018] FIG. **5** shows an exemplary catheter cleaning device in section view.

[0019] FIG. **6** shows a side view of an exemplary catheter cleaning device.

[0020] FIG. **7** shows a top view of an exemplary catheter cleaning device.

[0021] FIG. **8** shows an exemplary catheter cleaning device in the "open" position, with a measurement of the open position shown.

[0022] FIG. **9** shows an exemplary male luer with measurement of its diameter.

[0023] FIG. **10** shows a male luer entering an exemplary catheter cleaning device.

[0024] FIG. **11** shows a male luer locked into an exemplary catheter cleaning device.

[0025] FIG. **12** shows a top view of a male luer inserted and locked into an exemplary catheter cleaning device.

DETAILED DESCRIPTION OF THE INVENTION

[0026] The present invention provides catheter cleaning devices that are effective at reducing microbial contamination of a catheter port entry. The catheter cleaning devices of the invention reduce the potential for introducing infection into a patient via a catheter port entry. The catheter cleaning devices of the invention reduce microbial contamination at a catheter port entry by continually cleaning the port entrance by bathing it in an antimicrobial solution. The catheter cleaning devices also incorporate scrubbing surfaces that function to scrub the catheter connection as well as apply antimicrobial solution. Thus, the catheter port is bathed in antimicrobial solution, keeping the parts aseptic and clean.

[0027] As disclosed herein, a device has been developed that is designed to be used with a needleless intravenous system that will ensure the catheter hub is always disinfected regardless of the technique used to connect the catheter or lack of catheter care. This device also decreases the incidence of hub contamination, catheter lumen microbial colonization, and therefore, the risk for CRBI. This antimicrobial barrier effectively prevents endoluminal catheter contamination. A previous hub model that incorporated a chamber of 3% iodinated alcohol into which a needle would pass prior to insertion into the catheter was effective in the prevention of endoluminal catheter microbial colonization both in vitro and in vivo (Segura et al., *J. Clin. Microbiol.* 27:2656-2659 (1989); Segura et al., *J. Clin. Microbiol.* 28:2551-2554 (1990); Segura et al., *Ann. Surg.* 223:363-369 1996)).

[0028] Based on the results of a meta-analysis of eight studies and several more recent investigations, results have shown that skin preparation with chlorhexidine (0.5% or 10% chlorhexidine gluconate alcohol solution or 0.5% or 2% chlorhexidine gluconate aqueous solution) is more effective than 10% povidone-iodine for prevention of bacterial colonization and CRBI (Chaiyakunapruk et al., *Ann. Intern. Med.* 136: 792-801 (2002); Maki et al., *Crit. Care Med.* 28:A42 (2000); Garland et al., *Pediatrics* 107:1431-1436 (2001); Casey et al., *J. Hosp. Infect.* 54:288-293 (2003)), current standard of care now includes disinfection of the catheter hub with chlorhexidine (Northwestern Memorial Hospital (NMH) nursing protocol; Inoue et al., *JPEN* 16:581-585 (1992); Bouza et al., *J. Hosp. Infect.* 54:279-287 (2003)).

[0029] The catheter cleaning devices of the invention are intended to reduce colonization of the bacteria that reside on the surface of the needleless injection port entry area. When the mating luer fitting is inserted into the port, a person with

a central venous catheter (CVC) has to clean the entry port up to 42 times per week. Every time this is done there is a slight chance that bacteria will be introduced into the patients venous system. Improper cleaning of the port entry area allows the bacteria to enter the port. The present invention reduces the bacteria available for accidental insertion by continually bathing the needleless port in an antimicrobial solution such as isopropyl alcohol (IPA) and chlorhexidine (CHG) mix. This solution has been shown to be very effective against bacteria and other microorganisms.

[0030] Currently hospitals generally use a procedure to simply wipe the area of the port with three Chloraprep™ one-step wipes. These wipes are not easy to use on small objects and it is very subjective as to who and how the ports are cleaned in determining how well the bacteria count is reduced. Improper, hurried, or sloppy cleaning procedures will lead to a greater chance of bacterial ingress.

[0031] As used herein, a "bloodstream infection" refers to a blood culture that is positive for microbes such as bacterial or fungal microorganisms.

[0032] As used herein, a "catheter-related bloodstream infection" or "CRBI" refers to the occurrence of a bloodstream infection in a patient with a central venous catheter (CVC) in whom another source of infection is not wound, urine, respiratory, or intra-abdominal in origin.

[0033] As used herein, "catheter endoluminal colonization" refers to the presence of viable microorganisms such as bacteria or yeast, which can be grown in culture, on the inside walls of a catheter in the absence of positive blood cultures or any septic focus.

[0034] As used herein, a "catheter hub" refers to the junction between the intravenous catheter and intravenous tubing or other connection device.

[0035] In one embodiment, the invention provides a catheter cleaning device that is a cap design. The cap design for a catheter cleaning device is screwed on to a standard luer fitting of a needleless injection port.

[0036] An exemplary catheter cleaning device that is a cap design contains a body **10** and a connector/top **20**, as shown in FIG. **1**. The body **10** and connector/top **20** can be ultrasonically welded or adhesively joined together, for example, during final assembly after all the other parts are installed. The other parts of a catheter cleaning device that is a cap design include mobile frit **30** for slow transfer of cleaning solution, open cell scrubbing surface such as a wiping foam or sponges **40** to clean the port threads, O-ring **50** to seal the solution into its reservoir and a spring **60** to push frit **30** distally when the device is not installed onto a port. Reservoir **70** is for an antimicrobial solution such as IPA and CHG antimicrobial cleaning solution. The device cleans the CVC needleless port by screwing onto the luer fitting and pushing the mobile frit **30** up into reservoir **70**. The increased pressure in the reservoir forces the solution through the frit **30** and into the foam **40**, which in turn bathes the port opening in the antimicrobial solution and has a scrubbing action on the luer top, injection port piston, and threads. When a male luer is to be attached to a catheter, this device is removed, but can be tethered to the CVC port by an optional strap that runs between connector/top **20** and the port. The spring **60**, during removal of the device, pushes the frit **30** out, creating a slight vacuum, which draws the solution back into reservoir **70**. This vacuum limits the amount of solution evaporation when the cap is not installed onto a luer fitting. When the cap is then reattached to the luer, the frit **30** is again forced into reservoir **70** and the solution is forced into frit **30** and foam **40**, re-bathing the needleless port in antimicrobial solution. As the frit **30** is pushed further into reservoir **70**, the device can optionally contain a window to observe a visual indicator, in which O-ring **50**, which can be colored to facilitate visualization, can be visualized through a clear section on the side of body **10**, indicating the antimicrobial solution is low in volume and a new cap should be installed. The frit **30** and scrubbing foam **40** and the positive pressure on the antimicrobial cleaning solution continually bathe the port entrance. The negative pressure from the reservoir limits evaporation of the cleaning solution when not attached to the catheter port.

[0037] In one embodiment, the invention provides a catheter cleaning device, comprising a body having a cavity; a movable frit disposed in the cavity, whereby the frit is positioned to form a reservoir in the cavity; a spring disposed in the reservoir; an o-ring disposed between the frit and the wall of the cavity; and a scrubbing foam disposed in the cavity proximal to the frit and distal to the reservoir. The catheter cleaning device can further comprise a window positioned to indicate the position of the frit in the cavity. The catheter cleaning device can further comprise an antimicrobial solution dispersed in the reservoir.

[0038] In another embodiment, the invention provides an injection port cap, comprising a body having a cavity extending from a distal end to a proximate end of the body; a movable frit located within the cavity so as to form a reservoir between the frit and the proximate end of the body; a biasing element arranged to urge the movable frit towards the distal end of the body; and an absorbent element located within the cavity adjacent the distal end of the body. In such an injection port cap, the frit can be comprised of a porous material.

[0039] In an injection port cap of the invention, the biasing element can comprise a spring, for example, a helical spring, which can be located within the reservoir. An injection port cap of the invention can contain an absorbent element comprising a sponge.

[0040] In an embodiment of an injection port cap of the invention, the frit can be configured to provide a fluid pathway between the reservoir and the absorbent element. The liquid in the reservoir of an injection port cap can be forced through the frit to the absorbent element when the frit is moved against the biasing element towards the proximate end of the body. Generally, the cavity of the injection port cap of the invention has a substantially cylindrical shape.

[0041] In an injection port cap of the invention, the absorbent element can be located along at least a portion of a circumference of the cavity adjacent the distal end of the body. The body of an injection port cap can further comprise a window positioned to indicate a position of the frit or to indicate the level of liquid in the reservoir.

[0042] In an injection port cap, the cavity can comprise a closed end at the proximate end of the body and an opening at the distal end of the body. In such an injection port cap, the reservoir can be located between a top surface of the frit and the closed end of the cavity. Generally, the opening of the cavity of an injection port cap is sized to accommodate a catheter. In a particular embodiment, the opening of the cavity can further comprise screw threads adjacent the distal end of the body, for example, where the screw thread are configured to accommodate a luer fitting of a needleless injection port.

[0043] In an injection port cap of the invention, the cap can further comprise a sealing member located between a side surface of the frit and an inner surface of the cavity. For

example, the sealing member can comprise an elastomer o-ring located around the side surface of the frit. An injection port cap of the invention can further comprise an antimicrobial solution located within the reservoir.

[0044] In another embodiment, the invention provides a catheter cleaning device having a penetration design. The penetration design for a catheter cleaning device replaces the current needleless injection port with an all in one design. This device has the needleless injection port system included in the design.

[0045] An exemplary catheter cleaning device having a penetration design has parts that make up the port, which include device body **110** with luer threads included for attachment to the central venous catheter (CVC) and the feeding tube or male luer (see FIG. **2**). The other parts include bottom plug **120** that is in the male luer to the CVC and piston **130** that is compressed to allow fluid flow. The new parts of the device are the scrubbing surface/memory open cell foam **140**, scrubbing brushes **150** to assist cleaning of the incoming luer and displacement of scrubbing surface **140**, and sealing foam **160** to retain solution and protect against evaporation. Sealing foam **160** should remain moist and antimicrobial. Reservoir **170** contains antimicrobial solution.

[0046] The catheter cleaning device having a penetration design replaces the standard needleless port of the CVC so that the entrance to the catheter by the top of the piston **130** is continually bathed in antimicrobial solution such as IPA/CHG solution. When the male luer connector is needed, it is pushed through the sealing foam **160**, brushes **150**, and scrubbing foam **140** and screwed onto the female luer fitting. The scrubbing foam **140**, sealing foam **160** and brushes **150** are pushed to the radial sidewalls, and the antimicrobial solution is displaced into the reservoir **170**. When the male luer is removed, the scrubbing foam **140** resumes its position and covers the port opening and bathes it in an antimicrobial solution such as IPA/CHG solution. The brushes **150** and sealing foam **160** also resume their original positions to seal out the microbes. The antimicrobial solution re-penetrates brushes **150**, scrubbing foam **140**, and sealing foam **160**, cleaning them and making them antimicrobial surfaces. The scrubbing foam **140**, sealing foam **160**, and brushes **150** of the device protect the catheter entrance from microbial ingress.

[0047] In another embodiment, the invention provides a catheter cleaning device, comprising a body having a cavity; a plug disposed in the cavity; a piston positioned proximal to the plug in the cavity; a scrubbing foam proximal to the piston; brushes proximal to the scrubbing foam; a seal proximal to the brushes; and a reservoir in the cavity adjacent to the scrubbing foam, whereby insertion of a male luer allows penetration through the scrubbing foam, brushes and seal and displacement of fluid into the reservoir. The catheter cleaning device can further comprise an antimicrobial solution dispersed in the scrubbing foam and brushes.

[0048] In yet another embodiment, the invention provides a catheter cleaning device comprising a body comprising a passageway extending from a proximate opening adjacent a proximate end to a distal end; a penetrable sealing element located adjacent the proximate end within the passageway; an absorbent element located within the passageway between the distal end and the penetrable sealing element; at least one brush located between the penetrable sealing element and the absorbent element; a luer connector located within the passageway between the distal end and the brushes; and a reservoir formed within the passageway between the luer connector and the penetrable sealing element. In such a catheter cleaning device, the luer connector can be a female luer connector. The penetrable sealing element of a catheter cleaning device can comprise absorbent foam.

[0049] In a catheter cleaning device of the invention, the penetrable sealing device can be configured to operate in a first position when a luer fitting is inserted within the proximate opening and in a second position when no luer fitting is inserted within the proximate opening. For example, the penetrable sealing element can compress radially when operating in the first position. The penetrable sealing device can be configured to reduce evaporation of a fluid within the passage way operating in the second position.

[0050] In a catheter cleaning device of the invention, the absorbent element can include a central opening having a major axis substantially in-line with a major axis of the passageway. An inner surface of the absorbent element along its central opening can be configured to contact a luer fitting positioned adjacent the luer connector. In another embodiment, a bottom portion of the absorbent element can be located adjacent a top portion of the luer connector.

[0051] The absorbent element of a catheter cleaning device of the invention can be at least partially impregnated with antimicrobial solution. The absorbent element of a catheter cleaning device can be configured to radially compress when a luer fitting is attached to the luer connector such that a portion of the antimicrobial solution travels from the absorbent element to the reservoir. The portion of the antimicrobial solution in the reservoir can be located adjacent to an interface between the luer fitting and the luer connector.

[0052] A catheter cleaning device can further comprise a piston located within the passageway and extending from the luer connector through the distal end of the body. In a catheter cleaning device, the penetrable sealing element can comprise foam. The absorbent element can comprise open cell foam.

[0053] In yet another embodiment, the invention provides a catheter cleaning device that has a pop open design. The pop open design for a catheter cleaning device bonds the newly designed cap to a currently produced luer activated needleless injection port/connector. This new combination unit is used instead of the current plain injection port on the CVC catheters.

[0054] An exemplary catheter cleaning device having a pop open cap design has the device body **210**, the fluid sheath **220**, and scrubbing surface/bathing foam **230**, as shown in FIG. **3**, depicted in the "closed" position. The body device **210** contains bumped sides that can be compressed so that the device body **210** is in the "open" position (depicted in FIG. **4**). The only other part in this design is the commercially available luer activated needleless valve/port/connector **240**. The bathing foam **230** has a membrane to limit evaporation of the cleaning solution that permeates the foam. Two pieces of bathing foam **230**, approximate half cylinders, are bonded to the device body **210** with the membrane side facing out or externally. This assembly is then bonded and sealed onto the commercially available needleless valve such that the foam parts are in contact with the needleless valve opening. This proximity will allow scrubbing foam **230** to scrub the valve opening on actuation and closure of the cap/device. Also, the constant contact with the valve opening will allow continual bathing with the antimicrobial solution such as IPA and CHG solution. The next step is bonding the fluid sheath **220** to the external surface of the device body **210** along the base to prevent leakage of antimicrobial solution and along the spines

on the body to ensure proper placement of the sheath. The fluid sheath **220** and device body **210** can be ultrasonically welded or adhesively joined together. This sheath acts as a second skin that helps contain the antimicrobial solution, closes the cap end on luer port removal, and blocks debris from entering into the part when the luer port is installed. Finally the antimicrobial solution is added to the scrubbing foam **230** internal to the membrane.

[0055] This final assembly is then used instead of a standard needleless port of the CVC so that the entrance to the catheter by the top of the needless valve/port/connector **240** is continually bathed in antimicrobial solution. When a luer needs to be connected to the port, the device is squeezed on the bumped sides, which splits open the bathing foam scrubbers **230** and reveals the female luer fitting in a cleaned condition (see FIG. **4**). The male luer is inserted and the sides are released, enveloping the connection in a protected environment. Upon completion of accessing the needleless valve, the male luer is unscrewed and removed, and the foam is compressed together over the needless valve opening, rebathing it in antimicrobial solution until the next access is needed. This closed position also protects the valve opening from direct contamination from external sources. The foam **230** protects the entrance from microbial ingress. The device body is a firmer plastic and, when the sides of the device are squeezed, the plastic deforms, forcing the two halves of the device open and allowing access to the luer valve. The fluid sheath is made of a very elastic material that stretches open from the force imparted on it from the plastic device body as it deforms.

[0056] An exemplary catheter cleaning device is depicted in FIG. **5**. Such an exemplary catheter cleaning device is also referred to herein as a "cap" or "AB cap." An exemplary catheter cleaning device was produced, as shown in FIGS. **6-12** and described in Example II.

[0057] In yet another embodiment, the invention provides a catheter cleaning device, comprising a body having a cavity and a compressible position; a scrubbing foam disposed in the cavity; wherein the scrubbing foam has a fluid impermeable side that faces outward from the cavity, and a needleless port disposed in the cavity. Such a catheter cleaning device can further comprise an antimicrobial solution dispersed in the scrubbing foam.

[0058] In still another embodiment, the invention provides a catheter cleaning injection port cap, comprising a body comprising a passageway extending from a proximate end to a distal end; the proximate end operable in a closed position and an open position; the body further comprising an actuating member configured to change the proximate end from the closed position to the open position; a plurality of separable absorbent elements located within the passageway adjacent the proximal end; and a fluid impermeable sheath covering at least a portion of an exterior of the body. In such a catheter cleaning injection port cap, the absorbent elements can be impregnated with an antimicrobial solution. The absorbent elements can form a substantially closed surface when the proximate end is operated in the closed position. The absorbent elements can be spatially separated from one another when the proximate end is operated in the open position.

[0059] In a catheter cleaning injection port cap of the invention, the proximate end can be configured to accommodate a luer fitting when operated in the open position. One or more of the absorbent elements can be configured to contact an exterior of a luer fitting being inserted in the proximate end. In a catheter cleaning injection port cap of the invention, the plurality of separable absorbent elements can include two substantially half cylindrical sponges, wherein the sponges are adjacent one another when the proximate end is operated in the closed position and separate from one another when the proximate end is operated in the open position.

[0060] The body of a catheter cleaning injection port cap of the invention can be constructed of a deformable material. The actuating member of a catheter cleaning injection port cap of the invention can comprise at least one compressible portion protruding radially outward from a major axis of the passageway. For example, when the at least one compressible portion is compressed, the proximate end is in the open position; and when the at least one compressible portion is uncompressed, the proximate end is in the closed position. The distal end of a catheter cleaning injection port cap can be bonded to a needleless valve. For example, a bottom surface of the absorbent element is adjacent an opening of the needleless valve when the distal end is bonded to the needleless valve.

[0061] The catheter cleaning devices of the invention can include antimicrobial solutions to clean and sanitize catheter port entries. In one embodiment, the antimicrobial solution is a mixture of isopropyl alcohol and chlorhexidine or aqueous chlorhexidine. For example, the antimicrobial solution can contain about 0.05% to about 10% chlorhexidine gluconate (CHG), particularly about 0.05% to about 4%, for example, about 0.1%, about 0.2%, about 0.5%, about 1%, about 2%, about 3%, about 4%, about 5%, about 6%, about 7%, about 8%, about 9% or about 10%. A particularly useful antimicrobial solution is about 2% chlorhexidine in 70% isopropyl alcohol. Other suitable alcohols can also be used or mixtures of alcohols. The alcohol generally ranges from about 50% to about 80%, in particular about 70% or 75% alcohol. Alternatively, an aqueous solution of chlorhexidine gluconate, in the range of about 0.5% to about 2% of CHG, can be used as an antimicrobial solution. Other suitable antimicrobial solutions include iodine and its derivatives, for example, iodinated alcohol, for example, 3% iodinated alcohol, and povidone-iodine, for example, a 10% solution, or other suitable concentrations having antimicrobial activity. Other suitable antimicrobial solutions include silver sulfadiazine or other antiseptics. It is understood that mixtures of various antimicrobial agents can also be used. These and other antimicrobial solutions are well known to those skilled in the art (Segura et al., *J. Clin. Microbiol.* 27:2656-2659 (1989); Segura et al., *J. Clin. Microbiol.* 28:2551-2554 (1990); Segura et al., *Ann. Surg.* 223:363-369 1996); (Chaiyakunapruk et al., *Ann. Intern. Med.* 136:792-801 (2002); Maki et al., *Crit. Care Med.* 28:A42 (2000); Garland et al., *Pediatrics* 107:1431-1436 (2001); Casey et al., *J. Hosp. Infect.* 54:288-293 (2003)), Inoue et al., *JPEN* 16:581-585 (1992); Bouza et al., *J. Hosp. Infect.* 54:279-287 (2003)).

[0062] While the catheter cleaning devices of the invention described above and depicted in FIGS. **1-4** show specific embodiments, it is understood by those skilled in the art that modifications of the devices can be made so long as the catheter port connections are bathed in an antimicrobial solution and reduce microbial contamination of a catheter port entry. One skilled in the art can readily determine suitable modifications of the catheter cleaning devices of the invention.

[0063] For any of the catheter cleaning devices of the invention, various modifications can be made to facilitate replen-

ishment or dispersal of antimicrobial solution to appropriate places within the device. For example, a valve system can be added to introduce fresh antimicrobial solution to the device in order to penetrate or cover the frits, foam, or surfaces of the devices. Optionally, the valve can have an aperture or iris, such as found in a camera, to seal off the valve top and clean it on opening. In addition, a pressure piston can be used to encourage fluid transfer to facilitate dispersal of the antimicrobial solution to needed locations within the device. In addition, a screw mechanism or detent system can be included to create pressure to facilitate movement of the antimicrobial solution. This can serve to increase fluid capacity of the catheter cleaning devices of the invention, particularly in the cap design device. Vents can also be included on the catheter cleaning devices of the invention to help transfer fluid from a reservoir to materials to be contacted with the antimicrobial solution such as the foams that wipe the threads for the cap design or the foam and brushes of the penetration design. In addition, a catheter cleaning device can include an additional reservoir of antimicrobial solution that can be used to replenish the solution available for cleaning catheter connections. For example, a reservoir can contain a seal or valve that allows infusion of antimicrobial solution into the device, for example, by holding the device in a particular position, or the solution can be infused by squeezing a compressible reservoir. Such a reservoir can also be combined with the modifications described above to facilitate replenishment or dispersal of antimicrobial solution in the catheter cleaning device.

[0064] Additional modifications of a catheter cleaning device of the invention can include foam formed around a needleless port to prevent additional loss of fluid. For example, the foam in the device can have finger like projections that reach down to the end of the threads of the luer, closer to the cylindrical body of the luer body. The fingers can be lightly compressed on an area to catch any loose fluid in the device and help soak it into the main body of the foam. This could greatly help fluid loss if the device is activated when upside down. In addition, the scrubbing surface made of foam or sponge can be designed to plunge deeper into the device to help wick up antimicrobial solution. In addition, coloration can be incorporated into the scrubbing surface or foam, or other components of the device, to help target the connecting luer into the appropriate position in the device. Furthermore, the foam can incorporate a color change that reflects evaporation of the antimicrobial solution, for example, evaporation of alcohol, which can be used to conveniently indicate a need to use a new device. In addition, modifications can be incorporated into specific devices suitable for the particular device.

[0065] For a catheter cleaning device having a cap design, the device can include a threaded frit that can be used to limit over tightening and over pressurization of the reservoir. Furthermore, the scrubbing surface/foam of the cap design can be omitted so as not to clean the threads of the luer fittings. In such a case, a seal is provided in place of the foam to retain the microbial solution in the device. Instead, the device provides antimicrobial solution to bathe the catheter connections without the scrubbing action of the foam.

[0066] For a catheter cleaning device having a penetration design, a plastic cap can be included to cover the opening to prevent evaporation and ingress of microbes. A catheter cleaning device having a penetration design can also include foam or sponges placed into the reservoirs to insure wicking action and full saturation of scrubbing foams. In addition, the scrubbing foams can optionally be omitted, relying on the brushes to seal and clean the port entrance.

[0067] For a catheter cleaning device having a pop open design, colored targets on the sides of the pop open device can be used to indicate where to push to activate/open the cap.

[0068] The invention additionally provides a catheter cleaning device that is a wiping cap that is suitable to clean existing needleless catheter components. Such a wiping cap is a sealed cap with foam inserts approximating the size of the luer systems. As with the catheter cleaning devices of the invention, the foam can be saturated with antimicrobial solution to clean the ends of needleless port. This design allows good coverage of the port entry area with antimicrobial solution. The device can be disposed of after each use, if desired. Such a device conveniently substitutes for the physical wiping of catheter ports as currently practiced by health care professionals and eliminates variability between health care professionals using current practice. In such a design, the open end can be covered by a cap to prevent evaporation of antimicrobial solution prior to use.

[0069] The invention also provides a catheter cleaning device, comprising a body having a cavity, the body having a closed end and an open end; a scrubbing foam disposed in the cavity, and an antimicrobial solution dispersed through the scrubbing foam.

[0070] The invention further provides a method of adapting a luer activated needleless valve by bonding a catheter cleaning injection port cap over an opening of the luer activated needleless valve. In a particular embodiment of the method, the catheter cleaning injection cap can comprises a body comprising a passageway extending from a proximate end to a distal end; the proximate end operable in a closed position and an open position; the body further comprising an actuating member configured to change the proximate end from the closed position to the open position; a plurality of separable absorbent elements located within the passageway adjacent the proximal end; and a fluid impermeable sheath covering at least a portion of an exterior of the body.

[0071] The invention additionally provides a method of inhibiting microbial infection in an individual by using a catheter cleaning device of the invention. The method is useful for inhibiting infection of an individual with non-viral, non-protozoal, non-mold human infectious organisms. Thus, the method is useful for inhibiting or preventing infection at a catheter site by decreasing the likelihood of infection with Gram positive, Gram negative or non-mold fungi such as yeast.

[0072] It is understood that modifications which do not substantially affect the activity the various embodiments of this invention are also provided within the definition of the invention provided herein. Accordingly, the following examples are intended to illustrate but not limit the present invention.

EXAMPLE I

Testing of Catheter Cleaning Device for Reducing Microbial Contamination of a Catheter Port Entry

[0073] This example describes testing the effectiveness of the catheter cleaning devices.

[0074] The outer portion a catheter cap of a CVC needleless port is swabbed with various amounts of microbial cultures. Particularly, representative microorganisms are selected from Gram positive, Gram negative and fungi. The microbial cul-

tures tested are *Staphylococcus aureus, Klebsiella pneumonia, Escherichia coli, Candida* species such as *Candida albicans*. Other microorganisms can similarly be tested, for example, *Staphylococcus epidermidis, Klebsiella planticola, Pseudomonas aeruginosa,* and the like. These and other human infectious microorganisms can be similarly tested.

[0075] The testing involves swapping the outer portion of a catheter cap (the portion through which the male luer will pass) with 2000 cfu's (colony forming units) of bacteria or fungi. Other amounts of microbial cultures can also be tested. Sterile tubing is connected to the device, using the male luer to the female portion contained within the device, for example with a catheter cleaning device having a penetration design. Saline is then infused and the effluent is plated and cultured to detect and quantify microbial growth.

[0076] Similar experiments are conducted with other devices of the invention by swabbing with bacteria or fungi the outer portion of the catheter connection to be used with a particular device. The catheter is then connected, and saline is infused and collected. The effluent is cultured to detect and quantify microbial growth.

EXAMPLE II

Generation of a Catheter Cleaning Device

[0077] This example describes the generation of an exemplary catheter cleaning device. Such a device is also referred to as a "cap" or "AB cap."

[0078] A catheter cleaning device or cap was designed to keep needleless luer valves clean by encapsulating them in a cleaning solution. A cap was attached to a standard production needleless luer valve that is able to be squeezed open for attachment of a male luer lock. The AB cap has three main components, the inner shell (white piece; see top view in FIG. **7**), the outer membrane sheath (foggy clear exterior covering; see top view in FIG. **7**), and foam brushes (yellow interior; see top view in FIG. **7**).

[0079] The AB cap was glued over a standard production needless luer valve, such as an InVision-Plus® needless luer valve (RyMed Technologies, Inc.; Franklin Tenn.). Any type of needless luer valve suitable for a catheter cleaning device can be used, including any other manufacturers of needless luer valves. The foam brushes abut up to the entrance of the needless luer (see FIG. **5**).

[0080] Based on the measurements of a typical threaded male luer lock and the opened AB cap, the luer easily passes into the device and reaches the plunger of the needleless luer valve (see FIGS. **6-12**). Furthermore, FIG. **8** shows that, with the luer open, the green plunger of the needleless injection valve can easily be seen while the foam brushes of the AB cap, positioned laterally, are not in a position to interfere with the attachment of the male luer. FIGS. **10**, **11** and **12** detail the male luer attachment to the needleless injection port and demonstrate that, once the AB cap is released, it envelopes the male luer until the process is reversed by removing the male luer.

[0081] Throughout this application various publications have been referenced. The disclosures of these publications in their entireties are hereby incorporated by reference in this application in order to more fully describe the state of the art to which this invention pertains. Although the invention has been described with reference to the exampled provided above, it should be understood that various modifications can be made without departing from the spirit of the invention.

What is claimed is:

1. An injection port cap, comprising:
- a body having a cavity extending from a distal end to a proximate end of the body;
- a movable frit located within said cavity so as to form a reservoir between the frit and the proximate end of the body;
- a biasing element arranged to urge the movable frit towards the distal end of the body; and
- an absorbent element located within the cavity adjacent the distal end of the body.

2. The injection port cap of claim **1**, wherein the frit is comprised of a porous material.

3. The injection port cap of claim **1**, wherein the biasing element comprises a spring.

4. The injection port cap of claim **1**, wherein the biasing element comprises a helical spring.

5. The injection port cap of claim **1**, wherein the biasing element comprises a helical spring located within the reservoir.

6. The injection port cap of claim **1**, wherein the absorbent element comprises a sponge.

7. The injection port cap of claim **1**, wherein the frit is configured to provide a fluid pathway between the reservoir and the absorbent element.

8. The injection port cap of claim **7**, wherein a liquid in the reservoir is forced through the frit to the absorbent element when the frit is moved against the biasing element towards the proximate end of the body.

9. The injection port cap of claim **1**, wherein the cavity has a substantially cylindrical shape.

10. The injection port cap of claim **9**, wherein the absorbent element is located along at least a portion of a circumference of the cavity adjacent the distal end of the body.

11. The injection port cap of claim **1**, wherein the body further comprises a window positioned to indicate a position of the frit.

12. The injection port cap of claim **1**, wherein the cavity comprises a closed end at the proximate end of the body and an opening at the distal end of the body.

13. The injection port cap of claim **12**, wherein said reservoir is located between a top surface of the frit and the closed end of the cavity.

14. The injection port cap of claim **12**, wherein the opening of the cavity is sized to accommodate a catheter.

15. The injection port cap of claim **12**, wherein the opening of the cavity further comprising screw threads adjacent the distal end of the body.

16. The injection port cap of claim **15**, wherein the screw thread are configured to accommodate a luer fitting of a needleless injection port.

17. The injection port cap of claim **1**, wherein the cap further comprises a sealing member located between a side surface of the frit and an inner surface of the cavity.

18. The injection port cap of claim **17**, wherein the sealing member comprises an elastomer o-ring located around the side surface of the frit.

19. The injection port cap of claim **1**, further comprising an antimicrobial solution located within the reservoir.

20. A catheter cleaning device comprising:
- a body comprising a passageway extending from a proximate opening adjacent a proximate end to a distal end;
- a penetrable sealing element located adjacent the proximate end within the passageway;

an absorbent element located within the passageway between the distal end and the penetrable sealing element;

at least one brush located between the penetrable sealing element and the absorbent element;

a luer connector located within the passageway between the distal end and the brushes; and

a reservoir formed within the passageway between the luer connector and the penetrable sealing element.

21. The catheter cleaning device of claim **20**, wherein the luer connector is a female luer connector.

22. The catheter cleaning device of claim **20**, wherein the penetrable sealing element comprises absorbent foam.

23. The catheter cleaning device of claim **20**, wherein the penetrable sealing device is configured to operate in a first position when a luer fitting is inserted within the proximate opening and in a second position when no luer fitting is inserted within the proximate opening.

24. The catheter cleaning device of claim **23**, wherein the penetrable sealing element compresses radially when operating in the first position.

24. The catheter cleaning device of claim **23**, wherein the penetrable sealing device is configured to reduce evaporation of a fluid within the passageway operating in the second position.

25. The catheter cleaning device of claim **20**, wherein the absorbent element includes a central opening having a major axis substantially in-line with a major axis of the passageway.

26. The catheter cleaning device of claim **25**, wherein an inner surface of the absorbent element along its central opening is configured to contact a luer fitting positioned adjacent the luer connector.

27. The catheter cleaning device of claim **20**, wherein a bottom portion of the absorbent element is located adjacent a top portion of the luer connector.

28. The catheter cleaning device of claim **20**, wherein the absorbent element is at least partially impregnated with antimicrobial solution.

29. The catheter cleaning device of claim **28**, wherein the absorbent element is configured to radially compress when a luer fitting is attached to the luer connector such that a portion of the antimicrobial solution travels from the absorbent element to the reservoir.

30. The catheter cleaning device of claim **29**, wherein the portion of the antimicrobial solution in the reservoir is located adjacent to an interface between the luer fitting and the luer connector.

31. The catheter cleaning device of claim **20**, further comprising a piston located within the passageway and extending from the luer connector through the distal end of the body.

32. The catheter cleaning device of claim **20**, wherein the penetrable sealing element comprises foam

33. The catheter cleaning device of claim **20**, wherein the absorbent element comprises open cell foam.

34. A catheter cleaning injection port cap, comprising:

a body comprising a passageway extending from a proximate end to a distal end;

the proximate end operable in a closed position and an open position;

the body further comprising an actuating member configured to change the proximate end from the closed position to the open position;

a plurality of separable absorbent elements located within the passageway adjacent the proximal end; and

a fluid impermeable sheath covering at least a portion of an exterior of the body.

35. The catheter cleaning injection port cap of claim **34**, wherein the absorbent elements are impregnated with an antimicrobial solution.

36. The catheter cleaning injection port cap of claim **34**, wherein the absorbent elements form a substantially closed surface when the proximate end is operated in the closed position.

37. The catheter cleaning injection port cap of claim **34**, wherein the absorbent elements are spatially separated from one another when the proximate end is operated in the open position.

38. The catheter cleaning injection port cap of claim **34**, wherein the proximate end is configured to accommodate a luer fitting when operated in the open position.

39. The catheter cleaning injection port cap of claim **34**, wherein one or more of the absorbent elements are configured to contact an exterior of a luer fitting being inserted in the proximate end.

40. The catheter cleaning injection port cap of claim **34**, wherein the plurality of separable absorbent elements include two substantially half cylindrical sponges, wherein the sponges are adjacent one another when the proximate end is operated in the closed position and separate from one another when the proximate end is operated in the open position.

41. The catheter cleaning injection port cap of claim **34**, wherein the body is constructed of a deformable material.

42. The catheter cleaning injection port cap of claim **34**, wherein the actuating member comprises at least one compressible portion protruding radially outward from a major axis of the passageway.

43. The catheter cleaning injection port cap of claim **42**, wherein when the at least one compressible portion is compressed, the proximate end is in the open position; and when the at least one compressible portion is uncompressed, the proximate end is in the closed position.

44. The catheter cleaning injection port cap of claim **34**, wherein the distal end is bonded to a needleless valve.

45. The catheter cleaning injection port cap of claim **44**, wherein a bottom surface of the absorbent element adjacent an opening of the needleless valve when the distal end is bonded to the needleless valve.

46. A method of adapting a luer activated needleless valve, comprising the step of bonding a catheter cleaning injection port cap over an opening of the luer activated needleless valve.

47. The method of claim **46** wherein the catheter cleaning injection cap comprises:

a body comprising a passageway extending from a proximate end to a distal end;

the proximate end operable in a closed position and an open position;

the body further comprising an actuating member configured to change the proximate end from the closed position to the open position;

a plurality of separable absorbent elements located within the passageway adjacent the proximal end; and

a fluid impermeable sheath covering at least a portion of an exterior of the body.

48. A catheter cleaning device, comprising a body having a cavity; a movable frit disposed in said cavity, whereby said frit is positioned to form a reservoir in said cavity; a spring disposed in said reservoir; an o-ring disposed between said

frit and the wall of said cavity; and a scrubbing foam disposed in said cavity proximal to said frit and distal to said reservoir.

49. The catheter cleaning device of claim **48**, further comprising a window positioned to indicate the position of said frit in said cavity.

50. The catheter cleaning device of claim **48**, further comprising an antimicrobial solution dispersed in said reservoir.

51. A catheter cleaning device, comprising a body having a cavity; a plug disposed in said cavity; a piston positioned proximal to said plug in said cavity; a scrubbing foam proximal to said piston; brushes proximal to said scrubbing foam; a seal proximal to said brushes; and a reservoir in said cavity adjacent to said scrubbing foam, whereby insertion of a male luer allows penetration through said scrubbing foam, brushes and seal and displacement of fluid into said reservoir.

52. The catheter cleaning device of claim **51**, further comprising an antimicrobial solution dispersed in said scrubbing foam and brushes.

53. A catheter cleaning device, comprising a body having a cavity and a compressible position; a scrubbing foam disposed in said cavity; wherein said scrubbing foam has a fluid impermeable side that faces outward from said cavity, and a needleless port disposed in said cavity.

54. The catheter cleaning device of claim **53**, further comprising an antimicrobial solution dispersed in said scrubbing foam.

55. A catheter cleaning device, comprising a body having a cavity, said body having a closed end and an open end; a scrubbing foam disposed in said cavity, and an antimicrobial solution dispersed through said scrubbing foam.

* * * * *

EXHIBIT C

United States Patent [19]

Genatempo et al.

[11] **4,440,207**

[45] **Apr. 3, 1984**

[54] **ANTIBACTERIAL PROTECTIVE CAP FOR CONNECTORS**

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[21] Appl. No.: **378,315**

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[52] **U.S. Cl.** ..... **150/52 R**; 206/206; 206/207; 604/256; 604/905

[58] **Field of Search** ..... 604/27-29, 604/265, 280, 283, 93, 256, 905, 187, 192, 198, 263; 215/228, DIG. 3; 150/52 R; 206/206, 207

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[57] **ABSTRACT**

An article of manufacture and a method are provided where a protective cap for a connector provides antibacterial effect to the connector by fixedly lining a chamber of the protective cap with an absorbent material retaining an antiseptic. By mating a skirt on the protective cap with a corresponding flange on a medical connector, a contamination proof seal is also provided which functions to limit contamination from the outside of the cap and retain a liquid antiseptic on the inside of the cap.

15 Claims, 3 Drawing Figures

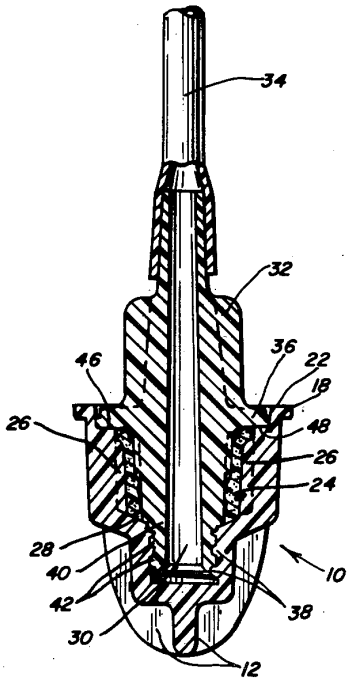


FIG. 1

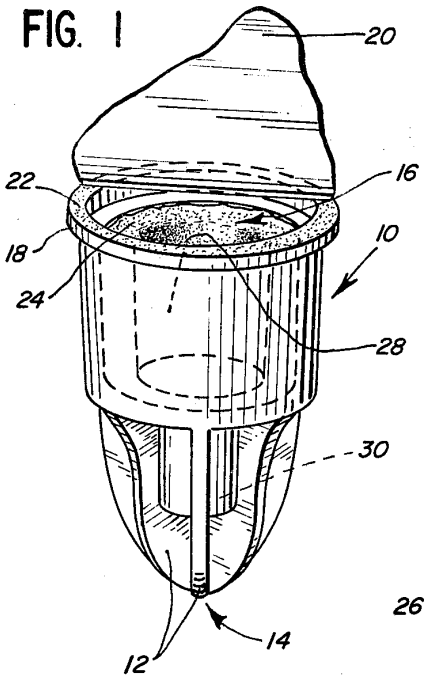
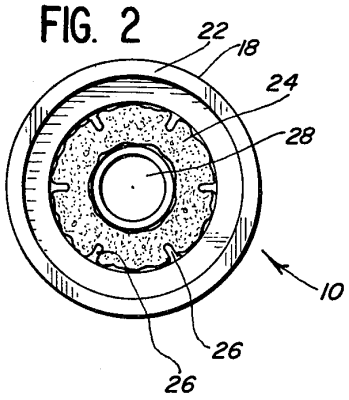


FIG. 2



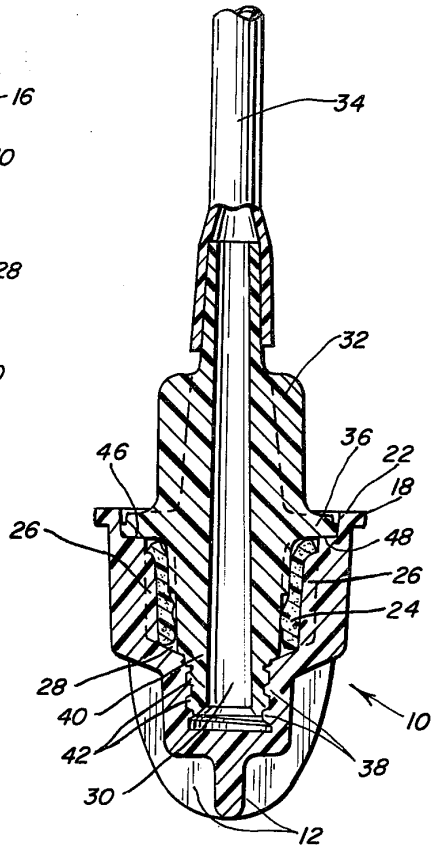


FIG. 3

ANTIBACTERIAL PROTECTIVE CAP FOR CONNECTORS

FIELD OF THE INVENTION

This invention relates to protective caps for medical connectors or ports and to closure systems for the ends of medical tubing or for ports on medical apparatus. The invention particularly relates to a protective cap for a medical connector or medical port opening which provides an antibacterial effect. An improvement of the present invention lies in reliably providing an antibacterial effect to a connector or port opening.

BACKGROUND OF THE INVENTION

Typical medical connectors in wide use are connectors for solution containers, administration sets and catheters. Medical procedures require a connection where the bioburden (i.e. bacterial population) is minimized. Protective caps containing an antibacterial agent can reduce the bioburden by providing a bacteriocidal or bacteriostatic effect to connector sites prior to use. A protective cap having an antibacterial effect is particularly desirable for components used in peritoneal dialysis, for example CAPD.

At the present time thousands of patients who have limited or nonexistent kidney function due to end state renal disease are being maintained by CAPD, and other forms of peritoneal dialysis.

In the CAPD procedure, connections between dialysis solution containers and administration sets which communicate with the peritoneal catheter must be made and broken, normally several times a day. Particularly when the patient is doing his own CAPD exchanges, there is the possibility that the sterility of the flow path between the various solution containers and the peritoneal cavity may be compromised. Airborne bacteria or the accidental contamination of an open connector by the patient can contaminate the flow path. The result of such a contamination can be peritonitis.

It is desirable to provide a protective cap for medical connectors such as CAPD connectors in particular, which securely receive and provide an antibacterial effect to the connector. For example, the Quinton Cap manufactured by Quinton Instrument Co., is sold, which contains liquid antiseptic such as povidone iodine freely flowing within the cap in its mode of use, to bathe the connector in antiseptic. However, this sytem requires filling of the system with antiseptic at the time of use, and thus involves a time-consuming process with the added disadvantage that the antiseptic can be spilled.

BRIEF SUMMARY OF THE INVENTION

The present invention provides a protective cap for a connector which securely receives and provides an antibacterial effect to the connector. At least a portion of the protective cap interior is lined with an absorbent material which retains an antiseptic. A connector covered by the protective cap is thus placed in an antibacterial environment made possible by contact of the connector with the antiseptic-retaining absorbent material, or from migration of the antiseptic, or both.

The protective cap of this invention is presently contemplated for use on solution container connectors, and particularly connectors communicating with the patient in peritoneal dialysis procedures. The liquid antiseptic such as povidone iodine, retained in the absorbent material lining within the cap, provides the antibacterial effect. However, use of the protective cap of this invention is by no means limited to the field of peritoneal dialysis. The protective cap of this invention may also be used for other medical applications or other procedures where it is desired to provide an antibacterial connection.

The protective cap of this invention is designed to securely receive a connector. The cap itself has a first, outer chamber which has an external opening defined by a skirt which allows engagement with a connector. An absorbent material lines the outer chamber and is affixed therein. The absorbent material retains an antiseptic which may be a liquid such as povidone iodine.

A second, inner chamber transversely smaller than the first chamber is positioned adjacent and open to the first chamber. The second chamber is designed to connect and receive the medical connector, the end of an administration set, or other types of tubes or ports. Internal threads are defined in the second chamber, and are designed to engage with external threads of a connector, to provide a threaded connection between the connector and cap. A flange on the connector may be received within the skirt of the protective cap to provide a seal, which additionally helps to reduce the possibility of contamination of the connector.

In manufacturing the cap, the first, outer chamber of a protective cap may be lined with the absorbent material. Ribs formed in the first chamber and directed towards the center of the first chamber project into the absorbent material and act as energy directing ribs, focusing ultrasonic energy to the absorbent material during an ultrasonic sealing step, whereby the absorbent material may be firmly welded to the inner chamber of the protective cap. Thereafter, an antiseptic is provided to the absorbent material, which takes it up and retains it.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of this invention, reference should now be had to the embodiment illustrated in greater detail in the accompanying drawings.

In the drawings:

FIG. **1** is a perspective view of the protective cap of this invention.

FIG. **2** is an end elevational view of the protective cap of this invention, showing the absorbent material lining and a series of inwardly directed ribs.

FIG. **3** is a longitudinal cross sectional view of a connector covered by the protective cap of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to the drawings, FIG. **1** is a perspective view of the protective cap **10** of this invention. Gripping fins **12** on the exterior portion of closed end **14** of protective cap **10** provide a convenient gripping surface.

External opening **16** of cap **10** is defined by skirt **18**, which also defines outer chamber **28**. A removable water vapor barrier such as peelable lid **20** of known design adheres to outer face **22** of skirt **18**, and is shown in the partially open position. Absorbent material **24** lines protective cap **10** and is fixedly attached to the inside of the protective cap.

When removable water vapor, microbial barrier lid **20** is closed, it completely covers and adheres to outer face **22** of skirt **18**. Thus when absorbent material **24** retains a volatile antibacterial agent, such as povidone iodine, loss by evaporation is greatly reduced. Alternatively, protective cap **10** may be placed in a preformed plastic blister which is covered by a removable water vapor barrier lid.

The end view of cap **10**, as shown in FIG. **2**, discloses a series of longitudinally positioned, inwardly directed ribs **26**, formed as part of skirt **18**. As shown in FIG. **3**, inwardly directed ribs **26** are located in first, outer chamber **28** of protective cap **10**. Second, inner chamber **30** adjacent, open to outer chamber **28**, is also shown.

Referring again to FIG. **2**, inwardly directed ribs **26** function as energy directors for ultrasonic welding of absorbent material **24** to the inner wall of skirt **18** (FIG. **3**). The cap wall, including ribs **26**, is preferably made of a thermoplastic material that will weld to the thermoplastic of absorbent material **24** when exposed to ultrasound energy. Absorbent material **24** is filled with an antiseptic after welding. Preferably, the wall of protective cap **10** is made of Hytrel ®5556 polyester manufactured by E. I. du Pont de Nemours & Co., and absorbent material **24** is made of polyether-based polyurethane, although substantially equivalent materials can also be used. A preferred antibacterial agent or antiseptic is povidone iodine.

Connector **32** is shown engaged by protective cap **10** in FIG. **3**. The connector **32** shown is a typical connector used with CAPD tubing sets. Tube **34** is shown extending from connector **32** to communicate, for example, with a Tenckhoff catheter implanted in the peritoneal cavity of a patient.

Skirt **18** of protective cap **10** is shown receiving flange **36** of connector **32**. Inner chamber **30** having internal threads **38**, cooperates to threadedly lock with external threads **42** of connector **32**.

The tube of absorbent material **24** is shown contacting main tubular portion **40** of connector **32**. Preferably, absorbent material **24** retains an antiseptic or antibacterial agent. In this manner, an antibacterial effect is provided to main tubular member **40** of connector **32**, as well as threads **42** through migration of the antiseptic.

Skirt **18** may be proportioned to form a tight, annular seal area **46** with flange **36**. Annular step or shoulder **48** may also be provided in skirt **18** and positioned to engage flange **36** for added sealing, and also to prevent overadvancement of connector **32** into cap **10**, which could damage the respective threads **42**, **38**.

The embodiment illustrated in FIG. **3**, including protective cap **10** and connector **32**, also comprises the antibacterial closure system of this invention. The closure system is effective in minimizing contamination of a connector before it is used or between uses.

The above has been offered for illustrative purposes and is not intended to limit the invention of this application, which is defined in the claims below.

What is claimed is:

1. A protective cap for a connector which securely receives and provides antibacterial effect to the connector, said cap comprising:

a first outer chamber having an external opening fixedly lined with absorbent material, said absorbent material retaining an antiseptic, said first outer chamber being defined by a skirt proportioned for sealing engagement with the connector; and

a second, inner chamber having a closed inner end, smaller than said first chamber, adjacent and open to said first chamber, having connecting means for receiving connecting means from said connector.

2. The protective cap of claim **1** in which said first chamber has a plurality of inwardly directed ribs which function as energy directors for ultrasonic welding of said absorbant material to said inner chamber.

3. The protective cap of claim **1** wherein said internal connecting means of said second inner chamber comprise internal threads for threaded cooperation with external threads.

4. The protective cap of claim **1** further comprising a plurality of gripping fins on an exterior portion of said protective cap.

5. The protective cap of claim **1** wherein said absorbent material is tube shaped.

6. The protective cap of claim **1** wherein said skirt of said protective cap is proportioned to securely engage a mating flange of a connector received therein.

7. A protective cap for an externally threaded, flanged medical connector which securely receives and provides antibacterial effect to the medical connector, said cap comprising:

a first, outer chamber having an external opening and having a plurality of inwardly directed ribs, an absorbent material lining said inner chamber, carried on the inner surfaces of said ribs, said absorbent material retaining a liquid antiseptic;

a second, inner chamber, smaller than said first chamber and adjacent and open to said first chamber, having internal threads for threaded cooperation with external threads of a connector; and

a skirt defined by said external opening to said first inner chamber for sealingly engaging a flange of a connector received in said cap.

8. The protective cap of claim **7** wherein said absorbent material is made of polyether-based polyurethane and said antiseptic is povidone iodine.

9. The protective cap of claim **7** wherein a removable water vapor barrier lid completely covers said external opening to said first chamber, and adheres to an outer face of said skirt.

10. The protective cap of claim **7** wherein said cap wall is made of polyester.

11. A protective cap for an externally threaded, flanged medical connector which securely receives and provides an antibacterial effect to the medical connector, said cap comprising:

a first, outer chamber having an external opening, a tubular thermoplastic, absorbent sponge, said outer chamber having a plurality of inwardly directed ribs serving as energy directors for ultrasonic welding of said tubular absorbent sponge to the inner surfaces of said ribs, said absorbent sponge carrying liquid antiseptic;

a second, inner chamber, smaller than said first chamber and adjacent and open to said first chamber, having internal threads for threaded cooperation with external threads of a connector;

a skirt defined by said external opening to said first inner chamber for sealingly engaging a flange of a connector received therein; and

a removable water vapor barrier lid covering and adhering to an outer face of said skirt.

12. The protective cap of claim **11** wherein said skirt of said protective cap defines an annular shoulder

which engages an annular flange on said connector to form an annular seal area.

13. An antibacterial closure system, said system comprising:

a protective cap for a connector;

said connector comprising a main tubular member having external connecting means;

said protective cap comprising:

a first, outer chamber having an external opening and fixedly lined with an absorbent material, said absorbent material retaining an antiseptic; and

a second, inner chamber having a closed end, smaller than said first chamber and adjacent to said first chamber and communicating therewith for receiving said external connecting means of said connector, the external opening of the first inner chamber being defined by a skirt, said connector defining a flange which is sealingly surrounded by said skirt.

14. The antibacterical closure system of claim **13** wherein said first chamber has a plurality of inwardly directed ribs serving as energy directors for ultrasonic welding to said absorbent material to said inner chamber.

15. The antibacterical closure system of claim **13** wherein said external connecting means of said connector comprise external threads, and wherein said internal connecting means of said second inner chamber of said protective cap comprise internal threads for receiving said external threads of said connector.

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